IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: METOPROLOL SUCCINATE END-PAYOR ANTITRUST LITIGATION	Civil Action No. 06-71 GMS
THIS DOCUMENTS RELATES TO:	
ALL ACTIONS	

END-PAYOR PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE CONSOLIDATED CLASS ACTION COMPLAINT OR, IF THAT MOTION IS DENIED, TO STAY THIS ACTION

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I. INTRODUCTION

This case arises from an anticompetitive scheme undertaken by Defendants AstraZeneca AB, AstraZeneca LP, AstraZeneca Pharmaceuticals LP and Aktiebolaget Hässle (collectively, "Astra" or "Defendants") to obtain, enforce and extend an unlawful monopoly for the manufacture and marketing of Toprol-XL® ("Toprol-XL"). The United States District Court for the Eastern District of Missouri recently found by clear and convincing evidence that Astra obtained the patents it claims for Toprol-XL by engaging in misconduct before the U.S. Patent and Trademark Office ("PTO"), and that the patents are invalid as a matter of law.

But that only tells half the story. Soon after it unlawfully obtained its patents, Astra also abused the statutory framework governing approval of generic drugs, known as the Hatch-Waxman Act, by listing its invalid patents in the U.S. Food and Drug Administration's ("FDA") *Orange Book*. These illegal listings allowed Astra to institute baseless patent litigation in 2003 and 2004 against prospective generic manufacturers KV, Andrx, and Eon, who sought FDA approval to market generic versions of Toprol-XL. Astra's sham patent litigation further delayed generic market entry by several years.

This class action seeks to recover the overcharges paid by Plaintiffs, a putative class of end-payors that paid supracompetitive monopoly prices for Toprol-XL. Plaintiffs instituted this litigation seeking redress for violations of federal and state antitrust statutes, state consumer protection laws, and state common law principles of unjust enrichment.

Astra has moved to dismiss Plaintiffs' federal antitrust claims based on a single, erroneous premise: that Astra's scheme to gain and enforce an unlawful monopoly had nothing

to do with the antitrust injury suffered by Plaintiffs. To accept this meritless argument, the Court must make factual findings, which it cannot do on a motion to dismiss. It also must discount or ignore several important allegations in the Consolidated Class Action Complaint: that the monopoly prices paid by Plaintiffs are the direct result of Astra's scheme to exclude generic competition by (a) obtaining invalid patents through misconduct before federal patent regulators, (b) manipulating and abusing the regulatory process governing approval of pharmaceuticals, and (c) filing baseless patent litigation to extend its unlawful monopoly. Such a conclusion would be contrary to Rule 12(b)(6) and established principles of federal antitrust law.

Astra posits that it was the Hatch-Waxman Act that foreclosed generic competition, and thus the Hatch-Waxman Act, not Astra's anticompetitive conduct, is the cause of Plaintiffs' injuries. This argument has been repeatedly made by defendant drug companies in similar cases – including within the Third Circuit – without success. And for good reason: all of the delays that Astra now blames on the Hatch-Waxman Act occurred as a direct result of Astra's illegal behavior. Astra's misconduct before the PTO and subsequent improper Orange Book listings forced prospective generic competitors to make Paragraph IV certifications instead of Paragraph I certifications, which likely would have allowed their ANDAs to be acted upon much sooner. Astra's filing of baseless patent infringement litigation triggered the Hatch-Waxman Act's 30-month automatic stay, causing further delay in generic approval. In other words, had Astra not manipulated and abused the patent and drug approval processes and filed baseless patent litigation, the Hatch-Waxman Act's provisions for a 30-month stay on final FDA approval and the accompanying prospect for tentative (versus final) FDA approval would not have become obstacles to generic competition. Having illegally triggered the regulatory process to

intentionally delay generic competition, Astra cannot now cast blame on that regulatory process as a means of insulating itself from antitrust liability.

Every district court within the Third Circuit, as well as two Circuit Courts of Appeal, have rejected Astra's theory that if a generic drug is not approved by the FDA during the 30-month stay period, the brand-name drug manufacturer is immune from antitrust liability. These courts recognize that anticompetitive conduct like that alleged here is the proximate cause of supracompetitive prices and the antitrust injury suffered by those that pay such prices. These courts recognize that a regulatory process is not an *independent* cause of injury when a bad actor set that process in motion in the first place; rather, the bad actor is still to blame.

In any event, Astra's motion also must be denied because it does not reach all of Plaintiffs' federal antitrust claims. Astra's motion argues that the Hatch-Waxman regulatory process alone prevented generic competition and, therefore, is the cause of Plaintiffs' injuries. However, there are substantial portions of Plaintiffs' claims that arise independently from facts associated with the Hatch-Waxman regulatory process. Thus, even if the Court were to accept Astra's proposed rule, which seeks to immunize brand-name drug manufacturers from antitrust liability unless the FDA pointlessly approves generic drugs that could not enter the market for up to 30 months in any event, additional aspects of Plaintiffs' federal antitrust claims still would survive.

Astra also moves this Court to exercise its discretion and decline supplemental jurisdiction over Plaintiffs' state law claims. However, the Court need not decide whether to exercise such discretion because supplemental jurisdiction is only one, alternative basis for jurisdiction over Plaintiffs' state law claims. Jurisdiction over these claims is undeniably proper

(and not within the Court's discretion) under the Class Action Fairness Act of 2005. Therefore, this aspect of Astra's motion also must be denied.

Finally, Astra moves to stay this action pending the Federal Circuit's review of the Eastern District of Missouri's ruling in the underlying patent litigation. Astra's request should be denied. Such a stay would visit obvious prejudice upon Plaintiffs, and Astra has made no showing of hardship or that its appeal has even the slimmest chance of success on the merits (it does not). This litigation should proceed to discovery following denial of the instant motion.

II. STATEMENT OF FACTS

A. The Hatch-Waxman Act

Congress enacted the Hatch-Waxman Act in 1984 to facilitate market entry of generic drugs that the FDA certifies as bioequivalent to corresponding brand-name drugs. *See* Consolidated Class Action Complaint ("CCAC") ¶¶ 10, 47. The Hatch-Waxman Act eliminated the requirement that a generic manufacturer file a costly and time-consuming New Drug Application ("NDA") in support of its proposed product. *Id.* ¶ 55. Under the Hatch-Waxman Act, a generic drug manufacturer can seek expedited FDA approval to market a generic version of a brand-name drug by filing an Abbreviated New Drug Application ("ANDA"), pursuant to 21 U.S.C. § 355(j), that relies on the earlier safety and efficacy data reported to the FDA in the initial brand-name NDA. *Id.*

In its ANDA, however, the generic manufacturer must demonstrate to the FDA that the proposed generic product does not infringe upon any of the patents associated with the brand-name product in the FDA publication "Approved Drug Products with Therapeutic Equivalence Limitations," known as the Orange Book. *Id.* ¶ 56. Generic ANDA filers must

certify that (1) the brand-name manufacturer has not filed any patent information with the FDA (a "Paragraph I Certification"); or (2) any patent or patents listed in the Orange Book have expired (a "Paragraph II Certification"); or (3) the generic manufacturer will not market its product until brand-name patent expiration on a future date (a "Paragraph III Certification"); or (4) the patent or patents listed in the Orange Book are invalid or the generic product will not infringe upon the brand-name product patents (a "Paragraph IV Certification"). *Id.* ¶ 57.

A Paragraph IV Certification creates a 45-day window of federal jurisdiction for the brand-name manufacturer to initiate a patent infringement action against the generic manufacturer. *Id.* ¶¶ 58-59. If the brand-name manufacturer elects to sue the generic manufacturer during this period, as Astra did here, the Hatch-Waxman Act automatically stays FDA approval of the generic ANDA for up to thirty months. *Id.* ¶ 59.

The principal purposes of the Hatch-Waxman Act are "to make available more low cost generic drugs [and] to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket government approval." *See* H.R. Rep. No. 98-857(I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48; s*ee also* Statement on Signing S. 1538 into Law, 20 Weekly Comp. Pres. Doc. 1359, 1360 (Sept. 24, 1984) (President's statement that the Hatch-Waxman Act "will provide regulatory relief, increase competition, economy in government, and best of all, the American people will save money, and yet receive the best medicine that pharmaceutical science can provide."). In other words, the Hatch-Waxman Act is "intended to promote competition between brand name and generic manufacturers." *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 535 (D.N.J. 2004).

As courts and commentators have frequently noted, however, the Hatch-Waxman

Act is, unfortunately, subject to frequent abuse and manipulation by brand-name drug manufacturers, particularly through sham patent infringement litigation. *See, e.g.*, Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 J. Legis. 21, 29-35 (2002). Despite the consumer relief principles that motivate the Hatch-Waxman Act, its automatic stay of ANDA approval for up to thirty months, and the general deterrent or delaying effect on would-be competitors of a costly patent infringement defense, provide a powerful incentive for brand-name manufacturers to file even meritless suits in order to extend their monopolies and deny purchasers the benefits of competition. *See Smithkline Beecham Corp. v. Geneva Pharms.*, 210 F.R.D. 547, 554 n.15 (E.D. Pa. 2002) (citing Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA: J.L. & Tech. 389, 415 (1999) ("the automatic thirty-month stay injunction inadvertently created a powerful incentive for the [pioneer drug maker] to list any and every patent related to a drug product irrespective of whether such patent was a significant barrier to legitimate competition"; in other words, it "enables a patent owner to prevent competition irrespective of the merits of the patent being asserted")).

B. Astra's Misconduct

This consolidated class action alleges violations of federal and state antitrust acts, state unfair deceptive practices acts, and the states' common law of unjust enrichment, arising from the manufacture and marketing of Toprol-XL. *See* CCAC ¶ 1. Plaintiffs are consumers and third party payors who paid for Toprol-XL in the United States during the period May 5, 2005 to the present. *Id.* ¶ 144. Defendants manufacture and market Toprol-XL, an "extended release"

form of the drug metoprolol succinate, for the treatment of angina, hypertension and congestive heart failure. *Id.* ¶¶ 2, 34-38.

Astra maintains two U.S. Patents relevant to Toprol-XL: No. 5,001,161 (the "'161 patent'") and No. 5,081,154 (the "'154 patent"). *Id.* ¶ 65. The gravamen of Plaintiffs' claims is that Astra unlawfully maintained a monopoly on Toprol-XL by, among other things, defrauding the PTO into issuing the '161 and '154 patents, by listing the patents in the Orange Book, and initiating sham patent infringement actions against its generic competitors. *E.g., id.* ¶¶ 3-4, 9, 63. A federal court has found by clear and convincing evidence that: (1) the '161 and '154 patents are unenforceable due to Astra's inequitable conduct in the prosecution of those patents before the PTO in failing to disclose a dispute over the inventorship of metoprolol succinate; (2) the '161 and '154 patents were invalid based on double-patenting; and (3) the '161 patent was invalid as anticipated. *See id.* ¶ 140; *In re Metoprolol Succinate Patent Litig.*, 2006 WL 120343, at *25-26 (E.D. Mo. Jan. 17, 2006) (Exhibit A hereto).

Thus, Astra's illegal scheme consists of three interrelated actions: (1) unlawfully obtaining the '161 patent and the '154 patent through intentional omissions and misrepresentations to the PTO; (2) listing invalid patents in the Orange Book; and (3) initiating and prosecuting baseless litigation to enforce patents that Astra knew were void *ab initio*.

Astra's unlawful actions delayed competing generic versions of Toprol-XL coming to market. As a result, Plaintiffs paid millions of dollars for Toprol-XL at prices significantly higher than what they would have paid if competing generic versions of metoprolol succinate were on the market. *Id.* ¶ 7.

On July 31, 2006, seven months after the patent litigation proceedings concluded

in the district court, and after Astra filed the instant motion, the FDA granted final approval to Eon Labs, Inc. to market a generic version of Toprol-XL in 25 mg. dosage, as well as tentative approval for the 50, 100 and 200 mg. dosages.[1] *See* Exhibit B hereto (FDA Approval Letter).[2]

III. STANDARD OF REVIEW

Astra, as the moving party, bears the burden of demonstrating that Plaintiffs fail to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6); *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991). When considering such a motion, the court must accept as true all allegations in the complaint and draw all reasonable inferences in the light most favorable to Plaintiffs. *Evancho v. Fisher*, 423 F.3d 347, 350 (3d Cir. 2005). "A complaint should be dismissed only if, after accepting as true all of the facts alleged in the complaint, and drawing all reasonable inferences in the plaintiff's favor, no relief could be granted under any set

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[1] Approval of the higher dosages was tentative, rather than final, because Eon was not the first Paragraph IV filer for those dosages. Had Astra not improperly listed the Toprol-XL patents in the Orange Book, of course, Paragraph IV certification would not have been necessary and Eon would be free to put all four dosages on the market now.

[2] *See also* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm (Drugs@FDA - A Catalog of FDA Approved Drug Products), confirming the FDA's approval of ANDA 076969, which was submitted originally by Eon Labs and which now inures to Sandoz, a company that acquired Eon Labs in 2005. For information about the merger, see www.ftc.gov/opa/2005/07/novartis and www.us.sandoz.com/eonlabs/index.html.

The Court can take judicial notice of the fact that a generic manufacturer's ANDA has been approved. *See In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (taking judicial notice that the FDA had not yet approved a generic manufacturer's ANDA). It is well settled that "[c]ourts may consider matters of public record" on a motion to dismiss. *Delaware Nation v. Pennsylvania*, 446 F.3d 410, 413 n.2 (3d Cir. 2006) (citation omitted). Public records include "published reports of administrative bodies" such as the FDA's Catalog of FDA Approved Products. *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1197 (3d Cir. 1993); *see also Rosenberg v. XM Ventures*, 129 F. Supp. 2d 681, 687 n.6 (D. Del. 2001) ("It is well settled that public records can be considered on a motion to dismiss.") (Sleet, J.) (citing *Pension Benefit Guar. Corp.*, 998 F.2d at 1197), *aff'd*, 274 F.3d 137 (3d Cir. 2001)).

of facts consistent with the allegations of the complaint." *Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts Inc.*, 140 F.3d 478, 483 (3d Cir. 1998). "The inquiry is not whether plaintiffs will ultimately prevail in a trial on the merits, but whether they should be afforded an opportunity to offer evidence in support of their claims." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 215 (3d Cir. 2002).

"[T]he existence of antitrust injury is not typically resolved through motions to dismiss." *Schuylkill Energy Resources, Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997). When the issue of antitrust injury is raised in a motion to dismiss, the court has "an obligation . . . to view the complaint as a whole and to base rulings not upon the presence of mere words but, rather, upon the presence of a factual situation which is or is not justiciable." *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 263 (3d Cir. 1998) (hereafter, *West Penn Power*); *see also Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 430 (D. Del. 2006) (Jordan, J.) ("[T]he presence of an antitrust injury must be determined after considering Defendants' conduct as a whole.").

Allegations of antitrust injury "are held to the pleading standard laid out in Federal Rule of Civil Procedure 8(a) which requires a short and plain statement of the claim." *U.S. Horticultural Supply, Inc. v. Scotts Co.*, No. 04-5182, 2006 U.S. Dist. LEXIS 36015, at *6 (E.D. Pa. June 1, 2006) (Exhibit C hereto) (citing *Lum v. Bank of Am.*, 361 F.3d 217, 228 (3d Cir. 2004)). "Courts 'should be extremely liberal in construing antitrust complaints.'" *Id.* (quoting *Knuth v. Erie-Crawford Dairy Coop. Ass'n*, 395 F.2d 420, 423 (3d Cir. 1968)).

IV. PLAINTIFFS SUFFICIENTLY ALLEGE ANTITRUST INJURY AND CAUSATION

Astra's assertion that "[i]f an antitrust plaintiff cannot *prove* antitrust injury, the claims must be dismissed," Defs.' Br. at 12 (emphasis added), unmasks its motion. Plaintiffs need not *prove* anything at this stage; all they need to do is *allege* an "injury of the type the antitrust laws were intended to prevent and that flows from that which makes Defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977).[3]

Pleading causation requires only an allegation of a "causal connection" between the defendant's conduct and the plaintiff's injury. *Barton & Pittinos v. SmithKline Beecham Corp.*, 118 F.3d 178, 181 (3d Cir. 1997). A plaintiff in an antitrust case does not need to allege that the defendant's conduct was the only possible cause of the plaintiff's injuries; rather, "[i]t is enough that the illegality is shown to be a *material cause* of the injury" and that the supracompetitive prices paid by Plaintiffs is "the type of loss that the claimed violations . . . would be *likely to cause*." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 125 (1969) (emphasis added).[4]

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[3] It bears mention that *Brunswick*, one of Defendants' principal cases, requires proof of antitrust injury only to recover treble damages, not to survive dismissal. *Brunswick*, 429 U.S. at 489.

[4] Indeed, even at trial Plaintiffs' burden of proving the causation prong of antitrust injury requires only "proof of *some* damage flowing from the unlawful [misconduct]; inquiry beyond this minimum point goes only to the amount and not the fact of damage. . . . [A] plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury . . . ." *Zenith*, 395 U.S. at 114 n.9 (citations omitted) (emphasis in original); *see also* 2 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 338a ("It is therefore enough that the antitrust violation contributes significantly to the plaintiff's injury, even if other factors amounted in the aggregate to a more substantial cause."). Accordingly, when considering antitrust injury causation, "doubts should be resolved against the person whose behavior created the problem." 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 651f (2d ed. 2002).

In pharmaceutical antitrust cases, it is settled law in this Circuit that when a brand-name drug manufacturer undertakes unlawful anticompetitive conduct to preclude generic competition, end-payor purchasers that then must pay supracompetitive prices suffer an "injury of the type the antitrust laws were intended to prevent...." *Brunswick Corp.,* 429 U.S. at 489. Indeed, the Third Circuit has observed, "[i]t is difficult to imagine a more formidable demonstration of antitrust injury." *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 401 (3d Cir. 2000). *See also In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d at 535 ("this Court finds that a reasonable trier of fact could conclude that but for the allegedly anti-competitive agreements, generic drugs may have entered the market sooner. . . . Plaintiffs have pled sufficiently the anti-competitive behavior (an agreement in restraint of trade) and injury (higher prices) required to state a *Sherman Act* violation.").[5]

As demonstrated below, Plaintiffs allege sufficiently the causal relationship between their antitrust injury and Astra's antitrust violations. Thus, Astra's motion should be denied.

A. Astra's Anticompetitive Conduct, Not the Hatch-Waxman Act, Is The Cause Of Plaintiffs' Injuries

1. Antitrust Injury And The Hatch-Waxman Act

A substantial majority of the federal courts – and *all* of the courts in this Circuit – that have addressed the issue presented here have flatly rejected Astra's argument. *See Xechem, Inc. v. Bristol-Myers Squibb Co.,* 372 F.3d 899 (7th Cir. 2004) (hereafter, "*Taxol II*"); *Andrx*

[5] Other Circuits agree. *See, e.g., In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 910 (6th Cir. 2003) ("The plaintiffs are consumers of the patented drug Cardizem CD, who allege that they were deprived of a less expensive generic product, forcing them to purchase the higher-priced brand name product, because of a *per se* illegal horizontal market restraint. Preventing that kind of injury was undoubtedly a *raison d'etre* of the Sherman Act when it was enacted in 1890.").

Pharm., Inc. v. Biovail Corp. Int'l, 256 F.3d 799 (D.C. Cir. 2001) (hereafter "*Cardizem CD*"); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751 (E.D. Pa. 2003); *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 274 F. Supp. 2d 937 (N.D. Ill. 2003) (hereafter, "*Taxol I*"), *rev'd on other grounds*, *Taxol II*, 372 F.3d 899 (7th Cir. 2004); *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540 (D.N.J. 2000) (hereafter, "*Ben Venue Labs*"); *Warner Lambert Co. v. Purepac Pharm. Co.*, 2000 WL 34213890 (D.N.J. Dec. 22, 2000) (Exhibit D hereto) (hereafter "*Neurontin*").[6] These courts – including three courts within the Third Circuit and two Circuit Courts of Appeal – reject the position adopted by Astra here and recognize that in antitrust cases such as this (a) fraudulent procurement of a patent and sham litigation brought to enforce such a patent – not FDA regulations – is the proximate cause of antitrust injury, and (b) neither tentative nor final FDA approval of a generic competitor is a prerequisite to antitrust standing.

These cases take a realistic view of the causation question and do not indulge the wooden, mechanistic approach championed by Astra, which it inartfully attempts to foist onto this case through a misapplication of the Third Circuit's decision in *West Penn Power*, 147 F.3d 256. *See* discussion *infra* at Part IV.B.1. Consistent with applicable Third Circuit teachings, these decisions demonstrate that allegations of antitrust injury, such as those made by Plaintiffs here, must be carefully considered in the unique context of pharmaceutical competition under the Hatch-Waxman Act. *See Cromar Co. v. Nuclear Materials and Equip. Corp.*, 543 F.2d 501, 506 (3d Cir. 1976) (where antitrust standing is challenged, "[e]ach case . . . must be carefully analyzed in terms of the particular factual matrix presented"). "[T]he defendant's reliance on

[6] To avoid any confusion arising from the fact that the same generic manufacturers' names sometimes appear in different cases (and in this case), some short-form citations refer only to the brand-name drug at issue in the case.

supervening government action or other independent cause must be examined closely." 2 Phillip E. Areeda et al., *Antitrust Law* ¶ 338b (2d ed. 2000).

Viewed in the proper context, it is plain that Astra and not the Hatch-Waxman process or FDA regulations is alleged to have caused the absence or delay of generic competition. It is solely due to Astra's wrongful conduct – specifically, its procurement of patents through misconduct, subsequent improper Orange Book listings, and consequent institution of sham patent infringement litigation – that the delay and uncertainty attendant to the Hatch-Waxman mandatory stay occurred in the first place. Astra blames the regulatory process for Plaintiffs' injuries, but *Astra itself triggered the regulatory process*. But for Astra's unlawful conduct, there would have been no 30-month stay or consideration of tentative approval, and FDA approval of the generics' ANDAs could have been "made effective *immediately*." 21 U.S.C. § 355(j)(5)(B)(i) (emphasis added).

In *Ben Venue Labs*, 90 F. Supp. 2d 540, Judge Walls of the District of New Jersey properly declined to allow a brand-name manufacturer to defeat antitrust standing by relying on the Hatch-Waxman regulatory process it had triggered in the first place. In that case, the counterclaim defendant, brand-name manufacturer Bristol, sought summary judgment on antitrust counterclaims brought by prospective generic competitors. Bristol advanced the same argument raised by Astra here: that antitrust standing cannot be established in the absence of prior FDA approval. *See id.* at 542-46. Like Astra does here, Bristol cited *West Penn Power* and argued that its competitors' injuries flowed not from Bristol's anticompetitive conduct, but rather from "the structure of the regulated industry." *Id.* at 545. Judge Walls soundly rejected this argument, recognizing that Bristol, not the FDA regulatory framework, caused the antitrust

injury:

> Bristol's argument ignores the reality of Hatch-Waxman. There is no dispute that by suing the generic defendants under the Hatch-Waxman Act, Bristol provoked the automatic moratorium of FDA approval of the generics' ANDAs. For Bristol to insist that its generic competitors have no standing because they are not in the market, *when Bristol itself foreclosed their access to it*, is meritless.

Id. (emphasis added). The same logic applies here. For Astra to insist that Plaintiffs lack standing because no generic competitor received tentative approval during the 30-month stay, when Astra itself created the circumstances that prevented tentative approval, is meritless.

Similarly in *Wellbutrin*, 281 F. Supp. 2d at 755-57, Judge Kauffman of the Eastern District of Pennsylvania rejected the same argument. There, as in the instant matter, a brand-name manufacturer (GlaxoSmithKline) moved to dismiss antitrust claims brought by end-payor-plaintiffs who alleged antitrust injuries arising from an improper Orange Book listing and subsequent sham patent litigation. Relying on Judge Walls' decision in *Ben Venue Labs*, Judge Kauffman rejected this argument, noting that GlaxoSmithKline itself "trigger[ed]" the 30-month stay and "initiated burdensome patent litigation," the effect of which was to create "an obstacle to the generic-drug companies' entry into the market." *Wellbutrin*, 281 F. Supp. 2d at 757.

Other courts have likewise rejected identical arguments, including Judge Lifland of the District of New Jersey in *Neurontin*, 2000 WL 34213890, at *8 ("Therefore, the generic manufacturer's injury does not merely result from the 'structure of a regulated industry,' but from the decision of the pioneer manufacturer to bring suit."), and the D.C. Circuit in *Cardizem CD*, 256 F.3d at 808 ("[W]e disagree with [the district court's] conclusion that any injury Biovail might plead would be caused by 'the existence of a troublesome statutory scheme. . . .'").

The causal relationship between Plaintiffs' antitrust injury and Astra's

anticompetitive conduct (its fraudulent procurement of patents, its Orange Book listings, and its sham patent litigation) is reinforced by common law concepts of causation, which inform concepts of antitrust standing.[7] As explained in the Restatement (Second) of Torts: "The intervention of a force which is a normal consequence of a situation created by the actor's negligent conduct is not a superseding cause of harm which such conduct has been a substantial factor in bringing about." *Restatement (Second) of Torts* § 443. *See United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244-45 (3d Cir. 2004) (applying § 443 causation analysis in a case alleging violations of the False Claims Act).

Here, Astra's unlawful conduct triggered its desired regulatory process and everything that flowed from such conduct – including the lack of FDA approval which it now claims is an independent cause that "cuts the causal chain" between the antitrust violation and Plaintiffs' injuries. To the contrary, Plaintiffs allege that Astra's conduct is the reason the generic manufacturers did not receive FDA approval during the mandatory stay period. Delay in regulatory approval is not "independent" of Astra's conduct; it is *because* of Astra's conduct.

2. The Institution Of Sham Litigation Changes Everything

District courts within the Third Circuit (as well as the Seventh and D.C. Circuits) recognize that a standing analysis must account for the many moving parts affecting generic manufacturers which become embroiled simultaneously in sham litigation and the FDA approval

[7] "The framework for understanding the issues of causation, remoteness of injury, and antitrust standing to sue for damages is provided by the common law." *Amey, Inc. v. Gulf Abstract & Title, Inc.*, 758 F.2d 1486, 1499 (11th Cir. 1985) (citing *Associated Gen. Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 533 (1983)); *Martorano v. PP & L Energy Plus*, 334 F. Supp. 2d 796, 798 (E.D. Pa. 2004) ("[T]he antitrust statutes are to be construed in light of their common-law background.") (citing *Associated Gen. Contractors*, 459 U.S. at 529-33), *aff'd*, 137 Fed. Appx. 491 (3d Cir. 2005).

process. This approach is consistent with the Third Circuit's teaching that "the antitrust standing inquiry is not a black-letter rule, but rather, is 'essentially a balancing test comprised of many constant and variable factors....'" *West Penn Power*, 147 F.3d at 264-65 (quoting *Merican, Inc. v. Caterpillar Tractor Co.*, 713 F.2d 958, 964-65 (3d Cir. 1983)). As Judge Lifland of the District of New Jersey noted, in light of the complex and constantly-shifting factors attendant to such circumstances, "the Supreme Court's requirement for a special 'causal connection' and 'directness' of injury must be *liberally construed* when dealing with regulatory conditions under the Hatch-Waxman Act." *Neurontin*, 2000 WL 34213890, at *8 (emphasis added).

Thus, these courts have acknowledged that improper Orange Book listings and subsequent sham litigation alter everything that comes afterward, including the motivation and priorities of generic manufacturers, the prospect of timely FDA approval, and ultimately the possibility for generic competition. These factors are inextricable parts of the causation chain, not a definitive break in that chain, as Astra suggests.

Courts are correct to consider the fact that generic manufacturers defending patent litigation – even patent litigation that is baseless and undertaken only to extend an unlawful monopoly – often must focus on defending such litigation instead of prosecuting their ANDA. *See Wellbutrin*, 281 F. Supp. 2d at 757 n.8 (rejecting argument that patent suits alleged to be baseless cannot be burdensome because "all litigation, particularly complex federal litigation involving patent issues, imposes some burden on the parties involved regardless of the merits of the claims"). Such a strategy is eminently logical, for even tentative approval is worthless if the patents in suit are declared to be valid or infringed. Judge Walls explicitly recognized this fact in *Ben Venue Labs*:

> [S]ince the beginning of litigation, the generic manufacturers have had little practical incentive to pursue even conditional agency approval. As Ben Venue remarked at oral argument, because FDA approval would be meaningless in the absence of a favorable court ruling on infringement or validity, the generic companies are better served to direct their resources toward defense of the infringement action. Under these circumstances, the court does not accept Bristol's premise that any lessening of competition is caused by the FDA's refusal to approve the pending ANDAs. The court finds that there is a definite, causative link between Bristol's induced moratorium and the counterclaimants' alleged antitrust injuries.

90 F. Supp. 2d at 545.

The identical logic was applied in *Wellbutrin*, 281 F. Supp. 2d at 757, where Judge Kauffman found that "[i]n the face of these patent lawsuits, it is reasonable to infer that Andrx and the other generic companies directed resources away from FDA approval and toward the defense of the infringement actions and, furthermore, that this reallocation of funds resulted in a delay of FDA approval."

The filing of sham litigation also may discourage FDA regulators from acting on an ANDA for the same reasons. Every year the FDA receives hundreds of applications for new medicines, new treatment options for existing medicines, over-the-counter drugs, and other pharmaceuticals. Over and above that, the FDA receives hundreds of ANDAs each year, and the number of applications submitted has been growing significantly in recent years.[8] In light of this heavy workload, and the FDA's stated mission to promote and protect public health "by ensuring that safe and effective drugs are available to Americans" (*FDA 2004 Report to the Nation*, at b,

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[8] FDA received over 1,100 ANDAs in 2003 and 2004 (the last two years for which statistics are available), and the number of generic drug applications submitted increased by 20% or more annually during the 2001-2004 period. *See* FDA Center for Drug Evaluation and Research, *2004 Report to the Nation* (hereafter, "*FDA 2004 Report to the Nation*"), at 30 (available at http://www.fda.gov/cder/reports/rtn/2004/Rtn2004.pdf). The Court may consider this published report of a federal agency for purposes of considering Astra's motion to dismiss. *See supra* note 2.

"Mission"), it is reasonable to infer that the FDA focuses its efforts on applications that will result in new and better drugs entering the market promptly. For both legal and practical reasons, generic drug applicants embroiled in related patent litigation *cannot* bring their drugs to market.[9] Because overburdened regulatory agencies like the FDA must exercise discretion in expending their resources, naturally these circumstances may lead the FDA to delay action on an ANDA during the pendency of potentially dispositive patent litigation. Indeed, one would expect – and probably want – the FDA to do just that.[10] Conversely, one would expect the FDA to address promptly those generic applications that are unhampered by related patent litigation. Indeed, this appears to be precisely what occurred here, as the FDA granted final approval to Eon's ANDA just seven months after the district court invalidated Astra's two Toprol-XL-related patents, well below the average time for FDA approval. *See FDA 2004 Report to the Nation*, at 28 (median generic approval time in 2004 was 15.7 months).

It follows logically that if the sham patent litigation brought by Astra caused the FDA not to approve the generic versions of Toprol-XL, plainly Astra has created this obstacle to generic competition and thereby "caused" Plaintiffs to suffer antitrust injury. *See Wellbutrin*, 281 F. Supp. 2d at 757 ("[O]ne could conclude that the intervening cause alleged by Defendants, the failure of Andrx to obtain FDA approval, was itself caused by Defendants' filing of the allegedly

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[9] FDA is well aware when patent litigation precludes final approval of an ANDA because applicants must so inform the FDA. *See* 21 C.F.R. § 314.107(f)(2).

[10] Indeed, Astra's motion to stay this action pending the outcome of its appeal in the patent litigation is premised on the very same logic. *See* Defs.' Br. at 3-4 & 25 ("This effort by the parties and the Court may very well be wasted because the outcome of the patent litigation . . . could require dismissal of this action or at least narrow the issues in this case.").

frivolous lawsuits.").[11]

Astra attempts to place a rosy gloss on the motivations of ANDA filers faced with must-win patent litigation, suggesting that the "incentive" of 180 days of exclusivity somehow erases all other countervailing concerns. *See* Defs.' Br. at 21. First, the Hatch-Waxman Act rewards the first applicant to *file* a Paragraph IV Certification with an ANDA, not the first to receive final approval from FDA. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(II). Thus, generic competitors are "incentivized" to be the first to file a complete ANDA with a Paragraph IV Certification, not "to pursue tentative approval of their ANDAs," as Astra wrongly contends. Defs.' Br. at 20 & 21. If a generic is the first-filer, the reward is guaranteed regardless of when FDA eventually approves the ANDA.

Moreover, although the Hatch-Waxman Act rewards Paragraph IV first-filers with 180 days of exclusivity, it most certainly does not do so for the purpose of "increas[ing] the settlement value of the patent litigation." *Id.* at 21. To the contrary, as several courts have recognized, the purpose of the exclusivity period is to compensate generic first-filers for bearing the onerous burden of defending patent infringement litigation like the baseless suits pursued by Astra here. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1075 (D.C. Cir. 1998); *Taxol I*, 274 F. Supp. 2d at 941; *SmithKline Beecham Corp. v. Geneva Pharm., Inc.*, 210 F.R.D. 547, 552 (E.D. Pa. 2002), *aff'd*, 71 Fed. Appx. 64 (Fed. Cir. 2003). Once the brand-name manufacture chooses to bring litigation, even sham litigation, the generic manufacturer is left with little choice but to prioritize winning the litigation over pursuing tentative FDA approval. *See Taxol I*, 274 F.

[11] That FDA may have granted tentative approval during the pendency of related patent litigation in a few instances, *see* Defs.' Br. at 20, does not refute this argument. At most, such action suggests that other, unknown factors must have influenced FDA in those particular cases.

Supp. 2d at 944 ("the prospect of financing a defense of inevitable infringement litigation discouraged" generic manufacturers from filing an ANDA); *Ben Venue Labs*, 90 F. Supp. 2d at 545 ("[B]ecause FDA approval would be meaningless in the absence of a favorable ruling on infringement or validity, the generic companies are better served to direct their resources toward defense of the infringement action."). At a minimum, Plaintiffs are entitled to discovery to determine whether that is what occurred here. Most importantly at this stage, the Court must draw the reasonable inference that this is what happened here, and therefore should deny the instant motion.

3. At This Stage, The Court Must Accept Plaintiffs' Theory Of Causation

The *actual* effect of the sham litigation on the motivations and actions of the generic manufacturers and the FDA in this case are factual questions for discovery that cannot be resolved on a motion to dismiss. *See Taxol I*, 274 F. Supp. 2d at 944 ("Although Defendant argues that Plaintiffs may not have received ANDA approval once they applied and that it may have taken years to obtain such approval . . ., these again are factual inquiries."). At the pleading stage, Plaintiffs are entitled to the inference that the generic manufacturers acted rationally by dedicating their efforts to defeating Astra's sham litigation as the first order of business, rather than expending resources pursuing ANDAs for drugs that, even if approved by the FDA, could not be brought to market because of the Astra-induced mandatory stay. Plaintiffs also are entitled to the inference that the FDA acted rationally by prioritizing the approval process for drugs that were not subject to a litigation-induced mandatory stay and therefore could be brought

to market immediately upon approval.[12] Drawing these inferences in favor of Plaintiffs, as is required on a motion to dismiss, leaves no question that Plaintiffs adequately allege that Astra caused Plaintiffs' antitrust injuries. *See Wellbutrin*, 281 F. Supp. 2d at 757 (denying motion to dismiss because "although it is possible that the frivolous lawsuits did not cause Plaintiffs' harm due to the lack of FDA approval, it is also possible that these lawsuits generated circumstances which are responsible for the lack of FDA approval itself"); *see also Swierkiewicz v. Sorema, N.A.*, 534 U.S. 506, 514 (2002) ("[A] court may dismiss a complaint only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.") (citation omitted).

Plaintiffs allege that Astra's conduct "prevented generic versions of Toprol-XL from entering the market," CCAC ¶ 3, thus causing antitrust injury. Astra asks the Court to conclude as *a factual matter* that Astra's baseless patent lawsuits had nothing to do with the unavailability of generic competition – a conclusion plainly at odds with Plaintiffs' complaint and the Rule 12(b)(6) standard. It is settled law that "disputed claims of causation and injury cannot be decided on a Rule 12(b)(6) motion." *Knevelbaard Dairies v. Kraft Foods, Inc.*, 232 F.3d 979, 989 (9th Cir. 2000); *see also In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d

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[12] Another reasonable inference to which Plaintiffs are entitled is that Defendants' anticompetitive conduct discouraged and/or delayed generic manufacturers other than those that actually filed ANDAs from developing their own generic versions of Toprol-XL. Absent Defendants' improper procurement of the '154 and '161 Patents, and their wrongful listing in the Orange Book, companies considering whether to submit an ANDA for generic Toprol-XL would not have had to weigh the potential for, and costs of, litigation over the '154 and '161 Patents or the possibility that Defendants would be able to obtain an automatic stay for up to thirty months. It is quite possible, even likely, that more manufacturers would have sought to develop a generic Toprol-XL, and that that development would have occurred earlier, had Defendants misconduct not prohibitively raised the costs of market entry.

198, 215 (3d Cir. 2002) ("The inquiry is not whether plaintiffs will ultimately prevail in a trial on the merits, but whether they should be afforded an opportunity to offer evidence in support of their claims."). The Court cannot dismiss Plaintiffs' allegations based on Astra's assertion that its conduct did not affect the availability of generic competition, as to do so would require the Court to draw inferences in favor of the moving party, rather than – as Rule 12(b)(6) requires – the non-moving party. *See Taxol II*, 372 F.3d at 902 ("A prediction that the plaintiff will be unable to meet its challenges [of proving generic competition would have entered the market] is not a good reason to dismiss a complaint under Rule 12(b)(6).").

Finally, even if it did turn out that the Hatch-Waxman process or the FDA somehow were partly to blame for the delay in generic entry, that would not diminish Plaintiffs' causation case against Astra because, at the very least, Astra's conduct shares the blame and thus is a "material cause" of Plaintiffs' injuries. *Zenith Radio Corp.*, 395 U.S. at 114 n.9. Allegations of antitrust causation that link anticompetitive conduct with antitrust injury need not include refutations of all alternative theories of causation to survive a motion to dismiss. *See In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d at 535; *Wellbutrin*, 281 F. Supp. 2d at 756. As the leading antitrust treatise explains, "to require proof that the illegal conduct was the *exclusive* cause of the plaintiff's injury would effectively deny private remedies, because multiple causes affect everyone." 2 Areeda et al., *Antitrust Law* ¶ 338a, at 317 (emphasis in original). Rather, "[i]t is . . . enough that the antitrust violation contributes significantly to the plaintiff's injury, even if other factors amounted in the aggregate to a more substantial cause." *Id.* Based on Plaintiffs' allegations, it is fair and reasonable to infer that Astra's abuse of the Hatch-Waxman process, if not entirely to blame for causing delayed generic competition, was at least a significant

contributor to it.[13] Therefore, Astra's motion to dismiss should be denied.

4. Astra's Proposed Rule Would Make Antitrust Standing A Matter Of Chance

Astra suggests that there is (or should be) a *per se* rule that antitrust standing cannot exist in pharmaceutical litigation absent tentative FDA approval during the 30-month stay. As discussed above, this is not the law, nor should it be. If it were, antitrust standing would rest on the resources, energies, priorities, politics, whims and other factors affecting generic manufacturers' prosecution of ANDAs and the FDA's handling of them. As Judge Walls explained in *Ben Venue Labs*, were courts to find that tentative FDA approval is a mandatory prerequisite to standing in cases such as this,

> antitrust standing under the Hatch-Waxman Act would be wholly contingent on the vagaries of the timing of agency action. If the FDA acted immediately to grant conditional approval to an ANDA, the generic applicant would have standing to bring antitrust claims. But if, as here, the patentee beat the applicant to the punch by filing a motion to dismiss before FDA approval, the generic maker would be denied antitrust standing. Such an anomalous and arbitrary result was not intended by the statute.

90 F. Supp. 2d at 545. Nothing in antitrust standing jurisprudence suggests that arbitrary facts or events should control. To the contrary, courts have long strived to imbue the law with stability and predictability. *See, e.g., Washington v. Heckler*, 756 F.2d 959, 968 (3d Cir. 1985) (Aldisert, C.J., concurring) ("Predictability in the law, or in Karl Llewellyn's phrase, 'reconability,' must exist so that private persons and public agencies, the legal profession, and trial courts may be

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[13] *See, e.g.*, CCAC ¶¶ 4 ("Defendants' unlawful conduct prevented less expensive generic versions of Toprol-XL from entering the United States market, thereby causing injury to Plaintiffs. . . ."); *id.* ¶ 10 ("Defendants instituted these [baseless patent infringement] suits to frustrate or delay market availability of generic bioequivalents."); *id.* ¶ 139 ("Defendants knew they could not expect success on the merits of these litigations, but utilized the Hatch-Waxman process to bar the generic manufacturers from entering the market.").

able to plan affairs accordingly, give proper advice, and decide cases in accordance with reasonably understandable principles."). Astra's proposed rule contravenes this long-held, meritorious principle. Thus, it must be rejected.

B. Defendants' Argument Relies On *West Penn Power*, A Case Grounded In An Entirely Different Factual and Legal Context, And Whose Reasoning Does Not Apply Here

Astra's heavy reliance on the Third Circuit's decision in *West Penn Power* is misplaced. Two district courts within the Third Circuit have been presented with arguments identical to Astra's, trying to extend *West Penn Power* to the pharmaceutical antitrust context, and both courts have flatly rejected the argument. *See Wellbutrin*, 281 F. Supp. 2d at 756; *Ben Venue*, 90 F. Supp. 2d at 545. As discussed below, their reasoning is sound.

1. *West Penn Power* Does Not Apply Here

For a number of reasons, *West Penn Power* has no application to this case. First, Astra ignores entirely that the *West Penn Power* opinion explicitly limits its holding to its unique factual context: "We make clear that this ruling is fact specific to the current climate in which the instant facts developed, namely, in the era of 'regulated electric utility monopolies'. . . ." 147 F.3d at 269; *see also id.* at 263 ("The present case arises in a factual context which is substantially different from that of most antitrust cases."). The logic of *West Penn Power* springs from an industry and regulatory framework that have *nothing* to do with the facts presented here, and, as found by the *Ben Venue* and *Wellbutrin* courts, nothing in the *West Penn Power* opinion suggests that its reasoning should be extended beyond its anomalous facts to contexts such as the one at bar.

The industry regulations in *West Penn Power* "frame[d] the issue" and ultimately

determined the outcome in that case. 147 F.3d at 263. Unlike the Hatch-Waxman framework at issue in the instant matter, the PUC regulations that caused the antitrust injury in *West Penn Power* were not "triggered" by the defendants' actions as part of their allegedly anticompetitive conduct (a proposed merger). Rather, the PUC regulations were in place for *every* potential competitor who wished to enter the market for providing electrical power service, and neither the requirements nor structure of the regulations could be impacted by other market players.[14]

By contrast, the requirements of the Hatch-Waxman Act, as well as the machinations of FDA action, change depending on the actions of brand-name manufacturers such as Astra. For example, if an ANDA filer wishes to compete with a brand-name manufacturer that has not listed any patents in the Orange Book, it makes a Paragraph I certification and FDA "approval may be made effective immediately." 21 U.S.C. § 355(j)(5)(B)(i). Even if the brand-name manufacturer has listed patents in the Orange Book and a Paragraph IV certification is made, FDA "approval shall be made effective immediately" unless the brand-name manufacturer files a timely patent infringement suit. 21 U.S.C. § 355(j)(5)(B)(iii). Only where the brand-name manufacturer chooses to file suit is there a 30-month stay and the potential for a contemporaneous tentative approval process. *Id.*

The brand-name manufacturer, here Astra, consciously triggers this otherwise dormant aspect of the regulatory structure and all its attendant delay and uncertainty. In doing so, it must bear responsibility for the direct consequences of its actions, including delayed generic

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[14] The same is true of the regulations in *Schuylkill Energy Resources,* 113 F.3d 405, another case cited by Astra. In addition, in that case the plaintiff was "neither a competitor nor a consumer in the relevant market" and therefore it could "not suffer antitrust injury." *Id.* at 415. No such infirmity is present here.

competition. Indeed, the ability of brand-name manufacturers to manipulate the Hatch-Waxman process so as to inhibit lawful competition has been the subject of much examination and criticism. *See* CCAC ¶ 12 (FTC Chairman stated that "an improper Orange Book listing strategy involves unilateral abuse of the Hatch-Waxman process itself to restrain trade").[15]

Thus, whereas in *West Penn Power* the PUC regulations "frame[d] the issue" (147 F.3d at 263), so too did the realities of the Hatch-Waxman Act frame the issues in *Ben Venue Labs*, *Wellbutrin*, *Neurontin*, *Cardizem CD*, *Taxol I* and *Taxol II*, *supra*, cases very similar to this case in which antitrust standing was upheld. Indeed, both the *Ben Venue* and *Wellbutrin* defendants argued to courts in the Third Circuit that *West Penn Power* should be extended to the Hatch-Waxman context, and both courts rejected that argument. *See Ben Venue*, 90 F. Supp. 2d at 545 (stating that defendant's analogy of Hatch-Waxman regime to PUC regime at issue in *West Penn Power* "ignores the reality of Hatch-Waxman"); *Wellbutrin*, 281 F. Supp. 2d at 756 (interpreting *West Penn Power* as permitting dismissal *only* where "an independent cause *fully accounts* for the plaintiff's alleged injury and breaks the causal connection between the alleged antitrust violation and the plaintiff's injury") (emphasis added).

Those courts recognized that brand-name manufacturers who trigger a process that

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[15] The *West Penn Power* court also found it significant that the plaintiff had not pled that the PUC *ever* would have granted the potential new competitor permission to enter the market, absent the alleged misconduct of the defendants. 147 F.3d at 267-68. Indeed, the court noted that there were "no facts averred in the complaint which even permit us to speculate as to the likelihood of the PUC granting certification...." *Id.* No such pleading deficiency exists here, where Plaintiffs have alleged that, but for Astra's misconduct, the FDA would have approved generic Toprol-XL, and it would have done so earlier. *See, e.g.*, CCAC ¶¶ 11, 125, 134. Furthermore, in *West Penn Power* the regulatory application was withdrawn, so there was no objective evidence of whether it ever would have been granted. 147 F.3d at 269. By contrast, here one generic Toprol-XL already has been approved, so there will be no need to speculate as to whether approval ever would have happened.

forces delay, expense and uncertainty onto generic competitors cannot then turn around and point to that process as a reason to bar antitrust standing. *See, e.g., Ben Venue Labs*, 90 F. Supp. 2d at 545 ("For Bristol to insist that its generic competitors have no standing because they are not in the market, when Bristol itself foreclosed their access to it, is meritless.").

Viewing this case within its specific factual context, as Third Circuit law requires, it is plain that *West Penn Power* does not allow Astra to achieve its goal. In this case, it is Astra's conduct – not some generally applicable, ever-present regulatory structure such as PUC regulations – that brought about the misconduct before the PTO, the improper Orange Book listings, the Paragraph IV certifications, the baseless patent infringement litigation, and the delayed FDA approvals. But for Astra's conduct, these obstacles to generic competition would not have existed. Unlike *West Penn Power*, where generally applicable regulations "cut[ ] the causal chain," 147 F.3d at 268, in this case the causal chain leads directly to Astra's conduct. *Cf. City of Long Beach v. Standard Oil Co. of Cal.*, 872 F.2d 1401, 1408 (9th Cir. 1989) (finding antitrust injury where companies conspired to maintain low price for oil, and rejecting argument that federal price control programs, and not the companies' actions, were the legal cause of the alleged injury because the companies' actions caused the price ceilings to be set artificially low in the first instance).

2. Astra's Other Cases Are Similarly Unpersuasive

As noted above, Astra is unable to find a court in the Third Circuit that has treated *West Penn Power* as it would like. Thus, Astra would have the Court look elsewhere. But to the extent that Astra's cases interpret *West Penn Power* differently than the courts within the Third Circuit, those cases are inapposite.

For example, in *Bristol-Myers Squibb Co. v. Copley Pharmaceutical, Inc.* (hereafter, "*Copley*"), 144 F. Supp. 2d 21 (D. Mass. 2000), the court relied on *West Penn Power* and *Andrx Pharmaceuticals, Inc. v. Friedman* (hereafter, "*Friedman*"), 83 F. Supp. 2d 179 (D.D.C. 2000), for its conclusion that "the statutory scheme, not Bristol's lawsuit, prevents Copley from entering the market." *Copley*, 144 F. Supp. 2d at 24-25. But as noted above and in the *Ben Venue* and *Wellbutrin* decisions in this Circuit, the Hatch-Waxman statutory scheme – specifically its provisions allowing brand-name manufacturers to force generic manufacturers into regulatory limbo – is not analogous to the generally applicable regulations at issue in *West Penn Power*.

Copley's reliance on *Friedman* further undercuts its value. *Copley* cited *Friedman* for its holding "that because the FDA had not tentatively approved Biovail's ANDA . . ., Biovail could not show a causal connection between the alleged collusion and Biovail's inability to enter the market." *Copley*, 144 F. Supp. 2d at 24 (citing *Friedman*, 83 F. Supp. 2d at 184). Yet, the D.C. Circuit later *reversed* the *Friedman* court on this very point. *See Cardizem CD,* 256 F.3d at 808-809 (D.C. Cir. 2001) ("[The district court] concluded that any injury Biovail may have suffered was caused not by the [alleged antitrust violation] but instead by the lack of FDA approval of its generic version of Cardizem CD and by the delay period prescribed by the Hatch-Waxman Amendments. We disagree."). With one of its primary foundations reversed and the other having been interpreted differently within its own (this) Circuit, *Copley* simply is not convincing.

Astra also relies on *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336 (S.D. Fla. 2004), a *summary judgment* decision. There, the court relied on the evidence

of record (or lack thereof) as the reason for granting summary judgment on five separate grounds, only one of which is the ground on which Astra relies. *See id.* at 1342 ("[T]here is only speculation, *rather than evidence*, that Abbott's filing of these lawsuits caused the alleged antitrust injury, namely, the prevention of generic market entry.") (emphasis added). Thus, this summary judgment decision is *not* applicable to this motion to dismiss, where the allegations of the complaint must be accepted as true. Indeed, the fact that *Terazosin* progressed to the summary judgment stage belies Astra's argument that Plaintiffs' allegations are insufficient as a matter of law.[16]

Finally, Plaintiffs respectfully suggest that, to the extent there may be judicial disagreement, the courts in the District of New Jersey, the Eastern District of Pennsylvania, the Seventh Circuit and the D.C. Circuit have the better of the argument, and that the district courts in *Copley*, *Terazosin*, and *Relafen* failed to consider the reality of patent litigation and the FDA approval process. As the majority of courts have concluded, causation is present where a pioneer drug company, not the FDA or its regulations, forces a generic company to navigate simultaneously complex federal patent litigation and an elongated Hatch-Waxman process. Astra asks the Court to view its conduct and the circumstances surrounding FDA approval

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[16] Astra also cites *In re Relafen Antitrust Litigation*, 286 F. Supp. 2d 56 (D. Mass. 2003), an inapposite case where antitrust standing was not at issue or even discussed. *Relafen* concerned concepts of speculative damages and whether claims were time-barred, *see id.* at 63, issues that are irrelevant to this case. Significantly, in *Relafen* the motion to dismiss was denied, and the passage Astra cites was merely one portion of the court's discussion in which it was drawing reasonable inferences in favor of the plaintiff. As it happens, the inferences that the plaintiffs in *Relafen* requested were different from the reasonable inferences Plaintiffs request here. Astra would prefer that this Court draw the *Relafen* inferences (which here would be favorable to Astra) rather than the inferences discussed above that are favorable to Plaintiffs. Rule 12(b)(6), of course, does not permit the Court to draw inferences in Astra's favor.

narrowly, as if causation is a formulaic matter amounting to "no tentative approval = no causation." This approach is incorrect. The Third Circuit "has emphasized that the antitrust standing inquiry is not a black-letter rule, but rather is 'essentially a balancing test comprised of many constant and variable factors.'" *West Penn Power*, 147 F.3d at 264-65 (citation omitted); *see also id.* at 263 (courts must "view the complaint as a whole" and base rulings "upon the presence of a factual situation which is or is not justiciable").

3. Conclusion

The private right of action in antitrust cases is intended to "increase[] the likelihood that a violator will be found out, greatly enlarge[] the penalties, and thereby help[] discourage illegal conduct." 2 Areeda ¶ 330b. Yet Defendants ask the Court to bar private rights of action in pharmaceutical antitrust cases where the FDA has not yet granted approval of a generic drug, even where the approval process itself is alleged to have been corrupted by the very anticompetitive conduct at issue. Adopting Defendants' proposed rule would provide brand manufacturers with further economic and legal incentives to make every effort, whether lawful or not, to delay the FDA's approval of generic versions of their drugs.[17] This perverse reading of antitrust law – which is not supported by any cases in this Circuit – would harm consumers and others who pay for prescription drugs, benefit manufacturers who seek to limit competition, and subvert the rationale and purpose of private antitrust litigation.

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[17] Brand-name manufacturers already have plenty of incentive to try to game the Hatch-Waxman process. *See supra* at Part II.A; CCAC ¶ 12 (citing FTC Chairman's Statement that "an improper Orange Book listing strategy involves unilateral abuse of the Hatch-Waxman process itself to restrain trade" and that "an NDA filer acting in bad faith . . . [has the] power to . . . delay[] generic entry and potentially cost[] consumers millions, or even billions, of dollars without valid cause.").

C. Astra's Motion Does Not Reach All Of Plaintiffs' Federal Antitrust Claims

Astra's motion rests entirely on the mistaken theory that Plaintiffs cannot establish antitrust standing without showing "that an ANDA had received tentative approval while the 30-month stay was in effect." Defs.' Br. at 9. On this point, Astra is wrong for a host of reasons, *see supra* at Parts IV.A-B, but Astra's theory also fails to address at least two facets of Plaintiffs' claims that have nothing to do with the 30-month stay. Therefore, even if the Court were to accept Astra's incorrect causation rule, at the very least Astra's motion should be denied as to these claims.

1. Even Before Astra's Institution Of Sham Litigation, Astra's Unlawful Procurement Of the '161 and '154 Patents And Improper Orange Book Listing Caused Antitrust Injury

By virtue of its inequitable conduct before the PTO, which already has been established in federal court by "clear and convincing evidence," Astra procured its invalid patents. CCAC ¶ 140. It then listed them in the Orange Book so that it could force generic manufacturers to file Paragraph IV certifications to the listed patents, which then opened the door for Astra to delay generic competition and unlawfully extend its ill-gotten monopoly.[18]

But for this anticompetitive course of action, generic manufacturers KV, Andrx and Eon (and other manufacturers) could have filed ANDAs containing Paragraph I certifications

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[18] *See* CCAC ¶ 4 (alleging Astra unlawfully obtained a monopoly for Toprol-XL, that in the absence of such conduct the '161 and '154 patents would not have been issued; and that Astra's unlawful conduct prevented less expensive generic versions of Toprol-XL from entering the market); *id.* ¶ 6 (Astra's maintenance of unlawful patents prevented generic versions of Toprol-XL from entering the market); *id.* ¶ 9 (Astra's "anticompetitive conduct includes improperly obtaining patents '161 and '154 for the purpose of preventing generic competition); *id.* ¶ 68 (patents '161 and '154 were invalid when issued due to misconduct before the PTO); *id.* ¶ 153 (intended effect of Astra's baseless patent filings was to delay the introduction of generic formulations of Toprol-XL into the market).

stating that no patents for the brand-name drug had been filed with the FDA. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I). Had such certifications been possible, competition would not have been hindered as it has been in this case.

Applicants making a Paragraph I certification need not contend with baseless patent litigation and its attendant delay and expense. When the FDA considers an ANDA containing a Paragraph I certification, it need not wait for the expiration of a 45-day period in which the brand-name manufacturer may file a patent suit, nor for the conclusion of any patent litigation, before approving an ANDA. Additionally, the FDA need not concern itself with whether the patent litigation will moot its efforts in working toward a tentative approval. Rather, when an ANDA contains a Paragraph I certification, "the approval may be made *effective immediately*." 21 U.S.C. § 355(j)(5)(B)(i) (emphasis added). Yet, because Astra had made its improper Orange Book listings prior to 2003 and 2004, when the generic manufacturers filed their ANDAs, Paragraph I certifications were not an option. Instead, the generic manufacturers were forced to make Paragraph IV certifications, thus making it possible for Astra to further delay generic competition by filing sham patent litigation.

The reasonable and obvious inference flowing from these circumstances is that but for Astra's misconduct, competition could have and would have entered the market much sooner.[19]

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[19] Plaintiffs' putative class period commences on May 5, 2005. This date is based on a sworn statement made by Eon in the underlying patent litigation that it would have been able to begin selling generic Toprol-XL at that time but for Astra's anticompetitive conduct. *See* CCAC ¶ 144; Eon's Second Am. Answer to Am. Compl. ¶ 122 (filed Dec. 7, 2004 in *In re Metoprolol Succinate Patent Litig.*, No. 4:04CV1197 RWS (E.D. Mo.)).

2. But For Astra's Anticompetitive Conduct, There Would Be No 180-Day Period of Exclusivity And Diminished Competition

In addition, Astra's motion notwithstanding, Plaintiffs still may recover for overcharges they must pay for the 180-day period during which, due to Astra's misconduct, all but one generic competitor will be barred from the market.

Astra's misconduct gave rise to a period of generic marketing exclusivity that would not have existed otherwise. By design, its improper Orange Book listing forced generic manufacturers to file Paragraph IV certifications to the listed patents, which automatically created a right to 180 days of market exclusivity. *See Mova Pharm. Corp.*, 140 F.3d 1060; 21 U.S.C. § 355(j)(5)(B)(iv)(I). Simply by listing bogus patents, Astra assured itself that at the end of the day, even if unsuccessful in litigation, it would get 180 days of competition with only one generic competitor. During this period, the extent of price competition will be substantially diminished, resulting in higher prices than would otherwise obtain. *See* CCAC ¶¶ 128-29. Had Astra not improperly listed its invalid patents in the Orange Book, generic manufacturers could have entered the market unhindered and prices would have fallen further than if only one generic competitor were competing with Astra. *See id.* (generic prices decrease, and the corresponding benefits to consumers increase, when additional generic competitors enter the market after expiration of the 180 day exclusivity period); *see also* 21 U.S.C. § 355(j)(5)(B)(i) (if applicant certifies that no patents are listed in the Orange Book, "the approval may be made effective immediately").

The overpayments Plaintiffs will incur during this 180-day period of reduced competition are a direct result of Astra's unlawful conduct before the PTO and its improper

Orange Book listings. Now that Eon has received final approval to market generic Toprol-XL, the 180-day exclusivity period will begin as soon as Eon markets the drug. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I). That Astra's conduct is the cause of this "significant threat of injury" cannot reasonably be debated. *Warfarin Sodium*, 214 F.3d at 399 (plaintiffs alleging claims under § 16 of the Clayton Act must only show there is "a significant threat of injury from [a] . . . violation of the antitrust laws") (quoting *Zenith Radio Corp.*, 395 U.S. at 130).

V. THE COURT CANNOT DISMISS PLAINTIFFS' STATE LAW CLAIMS BECAUSE JURISDICTION IS PROPER UNDER THE CLASS ACTION FAIRNESS ACT OF 2005

Even in the event that the Court were to dismiss Plaintiffs' federal antitrust claims, this case would be far from over. Astra asks the Court to exercise its discretion to decline jurisdiction over Plaintiffs' state law claims, *see* Defs.' Br. at 23-24, but respectfully, the Court has no such discretion. The Complaint properly alleges that jurisdiction over Plaintiffs' state law claims is proper under the Class Action Fairness Act of 2005 ("CAFA"), Pub. L. No. 109-2, 199 Stat. 4 (2005). *See* CCAC ¶ 14.

Under CAFA, "this Court has jurisdiction over a purported class action where [i] the amount in controversy exceeds $5,000,000, [ii] diversity of citizenship exists between at least one class member and one defendant, 28 U.S.C. § 1332(d)(2), and [iii] the number of class members is at least 100. *Id.* § (d)(5)(B)." *In re Intel Corp. Microprocessor Antitrust Litig.*, 2006 WL 1431214, at *1 (D. Del. May 22, 2006) (Farnan, J.) (Exhibit E hereto); *Robinson v. Holiday Universal, Inc.*, 2006 WL 470592, at *2 (E.D. Pa. Feb. 23, 2006) (Exhibit F hereto). All three of CAFA's requirements are satisfied in this case.

For purposes of evaluating whether there is an adequate amount in controversy, it

has long been the law that "the sum claimed by the plaintiff controls if the claim is apparently made in good faith." *St. Paul Mercury Indem. Co. v. Red Cab. Co.*, 303 U.S. 283, 288 (1938) (footnote citations omitted); *see also Golden v. Golden*, 382 F.3d 348, 354 (3d Cir. 2004) ("The amount [in controversy] need not be proven; rather, the amount is judged from the face of the complaint and is generally established by a good faith allegation."). To justify dismissal for failure to meet the jurisdictional minimum, "[it] must appear *to a legal certainty* that the claim is really for less than the jurisdictional amount. . . ." *Red Cab*, 303 U.S. at 289 (emphasis added, citation omitted); *see also In re LifeUSA Holding Inc.*, 242 F.3d 136, (3d Cir. 2001) ("A complaint will be deemed to satisfy the required amount in controversy unless the defendant can show to a legal certainty that the plaintiff cannot recover that amount.") (citing *Red Cab*, 303 U.S. at 289).

Here, the amount in controversy exceeds CAFA's $5,000,000 threshhold, as Plaintiffs alleged in their complaint. *See* CCAC ¶ 14.[20] Defendants have not rebutted this claim with any allegation or evidence that would show otherwise "to a legal certainty." *Red Cab*, 303 U.S. at 289. Thus, the first requirement of 28 U.S.C. § 1332(d)(2) is satisfied.

Second, the number of class members is at least 100. Plaintiffs believe there are hundreds of thousands of class members that have paid for Toprol-XL. *See* CCAC ¶ 146.

Finally, the parties are sufficiently diverse. Defendants are citizens of Sweden

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[20] Based on the nature of the commerce involved, there can be little doubt that a class of hundreds of thousands of end-payor purchasers could receive a judgment exceeding $5,000,000. *See* CCAC ¶ 6 ("Toprol-XL sales in 2005 were $1.29 billion, making it the number one revenue producing betablocker . . . and Astrazeneca's top-selling drug by volume."). Plaintiffs allege that absent Defendants' wrongful conduct, generic versions of Toprol-XL would have been available for 30% to 40% less than branded Toprol-XL (*see* CCAC ¶ 13).

and Delaware, either by virtue of their incorporation or maintenance of principal places of business. *See* CCAC ¶¶ 34-38. Representative plaintiffs are citizens of numerous states, including Alabama (CCAC ¶¶ 23, 29) Pennsylvania (CCAC ¶¶ 24, 25, 26, 30), Minnesota (CCAC ¶ 27), and Tennessee (CCAC ¶ 28). And it is anticipated that absent class members will be found throughout the United States and its territories. *See* CCAC ¶ 144 (defining nationwide class). Accordingly, the requirements of CAFA and 28 U.S.C. § 1332(d) are satisfied.[21]

VI. THE COURT SHOULD NOT STAY THIS ACTION

The Court should also deny Astra's request for a stay. At the outset, while the Court clearly has discretion to enter a stay, the Supreme Court has admonished that the exercise of such discretion should be "rare" and result in only a moderate delay to the non-moving party. *Landis v. N. Am. Co.*, 299 U.S. 248, 255-56 (1936). Further, if there is even a "fair possibility" that a stay would prejudice the Plaintiffs, then Astra has the burden of proving that the denial of a stay would result in a "clear case of hardship or inequity." *Dentsply Int'l, Inc. v. Kerr Mfg. Co.*, 734 F. Supp. 656, 658-59 (D. Del. 1990) (quoting *Gold v. Johns-Manville Sales Corp.*, 723 F.2d 1068, 1076 (3d Cir.1983)).

The prejudice to Plaintiffs from a delay is obvious. Even Astra concedes that Plaintiffs have an interest in the prosecution of their claims. *See* Defs.' Br. at 26. The underlying patent litigation has been pending for three years, and Defendants now propose additional, indeterminate delays in the form of an appeal and, presumably, petitions for rehearing and/or

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[21] None of the mandatory or discretionary exceptions to CAFA jurisdiction apply to this case. *See* 28 U.S.C. § 1332(d)(3)-(4); *Schwartz v. Comcast Corp.*, 2006 WL 487915, at *2-3 (E.D. Pa. Feb. 28, 2006) (Exhibit G hereto) (discussing the so-called "interests of justice," "home state controversy" and "local controversy" exceptions to CAFA jurisdiction).

certiorari. "When a case is delayed, a plaintiff may suffer prejudice as a result of the death or relocation of witnesses and the fading of witnesses' memories." *Shirsat v. Mut. Pharm. Co.*, 1995 WL 695109, at *2 (E.D. Pa. Nov. 21, 1995) (Exhibit H hereto) (citation omitted).

By contrast, Astra has made no clear showing of hardship or inequity. Nor has Astra demonstrated persuasively how a stay "may substantially affect" this lawsuit or "be dispositive of the issues." *Bechtel Corp. v. Local 215, Laborers Int'l Union*, 544 F.2d 1207, 1215 (3d Cir. 1976). Although Astra speculates that the appeal to the Federal Circuit will be successful, it makes no showing concerning its chances of success. *See e.g., Kemin Foods, L.C. v. Pigmentos Vegetales Del Centro S.A.*, 384 F. Supp. 2d 1334, 1341 (S.D. Iowa 2005) (refusing to stay litigation of counterclaims pending appeal of patent rulings to Federal Circuit because the arguments concerning trial court error were unpersuasive).[22]

Finally, even if the Court were inclined to grant a stay, any such stay should be tailored to the litigation burdens that Astra is now seeking to avoid. For example, while Astra predicts that "discovery would be extensive," this argument ignores the fact that Astra has already incurred the burden of collecting, reviewing, and producing much of this discovery during the litigation of the patent infringement case. Any additional burden of producing the same materials to the Plaintiffs would be *de minimis*. Thus, any stay in this case should permit Plaintiffs to obtain the discovery produced in the patent case.

[22] Statistically, the Federal Circuit Court of Appeals has reversed in only 13% of appeals from District Courts. *See* http://www.fedcir.gov/pdf/asooct2005.pdf.

VII. CONCLUSION

For the foregoing reasons, Astra's motion should be denied in all respects.

Dated: August 25, 2006

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CERTIFICATE OF SERVICE

I, J. Clayton Athey, hereby certify that on August 25, 2006, I electronically filed the foregoing End-Payor Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Consolidated Class Action Complaint Or, if That Motion is Denied, to Stay This Action with the Clerk of the Court using CM/ECF, and caused notification of such filing to be sent to the following counsel of record:

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EXHIBIT A

Slip Copy, 2006 WL 120343 (E.D.Mo.)
(Cite as: Slip Copy)

H

Briefs and Other Related Documents
Only the Westlaw citation is currently available.

United States District Court,E.D. Missouri, Eastern Division.

In re METOPROLOL SUCCINATE PATENT LITIGATION

No. MDL NO. 1620.

Jan. 17, 2006.

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MEMORANDUM AND ORDER

SIPPEL, J.

*1 Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, and AstraZeneca LP (collectively Astra) own patents claiming the pharmaceutically active compound metoprolol succinate and "sustained release" forms of that drug.[FN1] Defendants are drug makers seeking approval from the Federal Drug Administration to market extended release dosages of metoprolol succinate. Astra filed multiple lawsuits seeking declaratory judgments that Defendants' products infringe upon Astra's patents. Defendants have moved for summary judgment contending Astra's patents are invalid and/or are unenforceable. Because I find that the patents are invalid based on double patenting and anticipation I will grant Defendants' motion for summary judgment on those grounds. Because I find that Astra engaged in inequitable conduct during the prosecution of the patents I will also grant Defendants' motion for summary judgment on that ground.

FN1. The record before me established that AstraZeneca LP is the owner of the patents in suit. The legal standing of the other two Plaintiffs has never been formally explained by the parties.

Legal standard

Defendants have moved for summary judgment on Astra's claims. In considering whether to grant summary judgment, a district court examines the " pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any...." Fed.R.Civ.P. 56(c). Summary judgment is appropriate if the evidence, viewed in the light most favorable to the nonmoving party, demonstrates that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *Lynn v. Deaconess Medical Center,* 160 F.3d 484, 486 (8th Cir.1998)(citing Fed.R.Civ.P. 56(c)). The party seeking summary judgment bears the initial responsibility of informing the court of the basis of its motion and identifying those portions of the affidavits, pleadings, depositions, answers to interrogatories, and admissions on file which it believes demonstrates the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett,* 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

When such a motion is made and supported by the movant, the nonmoving party may not rest on his pleadings but must produce sufficient evidence to support the existence of the essential elements of his case on which he bears the burden of proof. *Id.* at 324. In resisting a properly supported motion for summary judgment, the plaintiff has an affirmative burden to designate specific facts creating a triable controversy. *Crossley v. Georgia-Pacific Corp.*, 355 F.3d 1112, 1113 (8th Cir.2004).

Patents are presumed to be valid. 35 U.S.C. § 282. Because of this presumption, a patent challenger must prove invalidity of a patent with clear and convincing evidence. *Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed.Cir.1991).

Background

Astra owns patents claiming the pharmaceutically active compound metoprolol succinate and sustained release forms of that drug.

Metoprolol succinate is an active chemical compound used in the treatment of angina, hypertension, and congestive heart failure. Metoprolol succinate was invented at Plaintiff Aktiebolaget Hassle's facilities in Sweden. Astra manufactures and markets different dosages of metoprolol succinate in "extended release" [FN2] forms under the brand name Toprol-XL®. Astra holds two United States patents that claim " sustained release" formulations of metoprolol succinate and metoprolol succinate itself. These patents are United States Patent 5,001,161 (the '161 patent) and United States Patent 5,081,154 (the '154 patent) respectively. Astra asserts that its Toprol-XL ® products are protected from infringement by these two patents.

FN2. Astra refers to its Toprol-XL® as an "extended release" drug in its Complaints against Defendants and in various documents that are part of the record in this case including its memorandum of law in support of its motion to dismiss Defendant KV Pharmaceutical's counterclaims (E.D. Mo. Cause No. 4:03CV592, Doc. # 31).

***2** Defendants KV Pharmaceutical Company (KV), Andrx Pharmaceuticals, LLC and Andrx Corporation (Andrx), and Eon Labs, Inc. (Eon) [FN3] are pharmaceutical companies who seek to market their own extended release dosages of metoprolol succinate. KV, Andrx, and Eon separately filed Abbreviated New Drug Applications (an ANDA) with the United States Food & Drug Administration (the FDA) seeking approval of their extended release metoprolol succinate formulations as the first step to placing these drugs on the market.[FN4] In their respective ANDAs, Defendants asserted that their extended release metoprolol succinate formulations have the bioequivalence of Astra's Toprol-XL®. Astra claims that Defendants' metoprolol succinate drugs are merely generic versions of Toprol-XL® and infringe upon Astra's '161 and '154 patents.

FN3. KV, Andrx, and Eon are collectively referred to as "Defendants".

FN4. Defendants KV Pharmaceutical, Andrx, and Eon each seek to market 25, 50, 100, and 200 mg strengths of their respective metoprolol succinate formulations.

The Federal Food, Drug and Cosmetic Act, codified in pertinent part at 21 U.S.C. § 355 and 35 U.S.C. § 271, (Hatch-Waxman Act), creates a safe harbor from claims of patent infringement for certain activities directed to preparing an ANDA. However, the filing of an ANDA seeking FDA approval to enter the market with a generic drug before the expiration of patents claiming the drug or its use is considered an act of infringement. 21 U.S.C. § 271(e)(2). In such a circumstance the owner of the patent is authorized to bring suit for injunctive relief to prevent the commercial manufacture, use, offer to sell, or sale of the generic drug within the United States. 21 U.S.C. § 271(e)(4).

Because Defendants seek to market their extended release metoprolol succinate drugs before the

expiration of Astra's '161 and '154 patents, Astra filed the present lawsuits seeking declaratory judgments of infringement.[FN5] Defendants have countered that their products do not infringe on Astra's patents and, in the alternative, that Astra's patents are invalid based on double patenting and inequitable conduct.

> FN5. Astra brought suit against Defendant KV Pharmaceutical in this Court. Astra's suits against Defendants Andrx and Eon were filed in the United States District Court for the District of Delaware. These lawsuits were transferred to this Court by the United States Judicial Panel on Multidistrict Litigation for consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407.

Specifically, Defendants assert that Astra's '161 and '154 patents are invalid for double patenting over earlier issued patents United States Patent 4,780,318 (the '318 patent) and United States Patent 4,957,745 (the '745 patent); and that the '154 patent is invalid for double patenting over the '161 patent. Defendants also argue that the '161 is invalid as anticipated by prior art under 35 U.S.C. § 102(b).

Additionally, Defendants assert that patents '161 and '154 are unenforceable based on inequitable conduct by Astra during their prosecution of the patents before the United States Patent and Trademark Office (USPTO). Defendants allege that named inventors of metoprolol succinate were intentionally misrepresented to the USPTO. Alternatively, Defendants assert that the three-year dispute between Astra and another drug company concerning inventorship of metoprolol succinate should have been disclosed to the USPTO.

Discussion

Invalidity based on double patenting

Defendants assert that Astra's '161 patent and '154 patents are invalid for obviousness-type double patenting. Obviousness-type double patenting, also referred to as nonstatutory double patenting (as distinguished from statutory double patenting under 35 U.S.C. § 101), is a judicially created doctrine that prevents the issuance of a patent on claims that are nearly identical to claims in an earlier patent. *Geneva Pharmaceuticals, Inc. v. GalaxoSmithKline PLC,* 349 F.3d 1373, 1377-78 (Fed.Cir.2003). This doctrine prevents patent applicants from extending their patent term for an invention beyond the statutory limits by claiming a mere obvious variant of the claims in a prior patent. *In re Emert,* 124 F.3d 1458, 1460 (Fed.Cir.1997).

***3** The public policy behind this doctrine is to allow the public to freely use a patent upon its expiration. *In re Longi,* 759 F.2d 887, 892 (Fed.Cir.1985) (citing *In re Zickendraht,* 50 C.C.P.A. 1529, 319 F.2d 225, 232 (C.C.P.A.1963)(Rich, J. concurring)). Not only should the invention claimed in the patent be available to the public upon its expiration "but also modifications or variants which would have been *obvious* to those of ordinary skill in the art at the time the invention was made...." *Id.*

In deciding whether a challenged patent is invalid for obviousness-type double patenting, a court must determine whether the claims of the challenged patent define an obvious variation of the claim in an earlier issued patent. *In re Emert,* 124 F.3d at 1461; *General Foods Corp. v. Studiengesellschaft Kohle,* 972 F.2d 1272, 1280 (Fed.Cir.1992)(double patenting principles extend to merely obvious variants of what has been patented). In order to compare claims of patents a court must construe what the claims are in each patent.

Claim construction

Defendants assert that Plaintiff's '161 patent and '154 patent are invalid based on double patenting of claim 8 of the '318 patent. Defendants originally stated that they would apply Astra's construction of the '161 patent for purposes of their invalidity motion. That was before Defendants learned how Astra construed the term "sustained release" in the claim of that patent. The meaning of the term " sustained release" is disputed by the parties as is the

construction of claim 8 of the '318 patent.

The United States Court of Appeals for the Federal Circuit has recently summarized and clarified the claim construction process in its decision in *Philips v. AWH Corp.*, 415 F.3d 1303 (Fed.Cir.2005).[FN6] The "claims of a patent define the invention to which a patentee is entitled to the right to exclude." *Id.* at 1312. The claims are of primary importance in the effort to ascertain what it is that has been patented. *Id.* The words of a claim are generally given their ordinary and customary meaning. *Id.* The meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question as of the effective filing date of the patent application. *Id.* at 1313. Importantly, the person of ordinary skill in the art is deemed to have read the claim term in the context of the claim as well as in the context of the entire patent, including the specification. *Id.*

> FN6. I have excluded all internal quotations and citations in my citations to *Phillips*.

To determine the meaning of a term in a field of art, a court "looks to those sources available to the pubic that show what a person of skill in the art would have understood the disputed claim language to mean." *Id.* at 1314. Those sources include intrinsic evidence, which encompasses the words of the claims themselves, the specification, and the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art. *Id.*

***4** Claims "must be read in view of the specification, of which they are a part." *Id.* at 1315. The specification is the single best guide to the meaning of a disputed term. *Id.* It is entirely appropriate for a court, in the course of claim construction, to rely heavily on the written description in the specification for guidance as to the meaning of the claims. *Id.* at 1317.

Although a court may refer to extrinsic evidence in the form of expert and inventor testimony, dictionaries, and learned treatises, these sources are less significant than the intrinsic record in determining the legally operative meaning of claim language. *Id.* Conclusory or unsupported assertions by experts as to the definition of a claim term are not useful to a court performing a claim construction. A court should discount an expert's testimony regarding the meaning of a claim term if it is clearly at odds with the claim construction mandated by the intrinsic evidence of the claims themselves, the specification, and the prosecution history. *Id.* at 1318.

Defendants assert that claim 8 of the '318 patent is a specific extended release formulation of metoprolol succinate. They argue that the claim in the '161 patent for "sustained release" formulations of metoprolol succinate is merely an obvious variant of claim 8. The claim of the '154 patent simply claims the compound metoprolol succinate. Defendants contend that the claims in the '161 and '154 patents are a genus of the species identified in claim 8 of the '318 patent and are therefore void for double patenting.

To determine whether the '161 and the '154 patents are invalid for double patenting over claim 8 of the '318 patent, the inventions claimed in each patent must first be construed. Because Defendants initially represented that the claim of the '161 patent was not in dispute a formal claims construction hearing was not held. As the positions of the parties crystalized during the summary judgment briefing it became clear that the parties did not agree to the construction of the term "sustained release" used in the '161 patent. The parties were clearly aware of this dispute and fully briefed and presented evidence in support of their construction of that term in their cross motions for summary judgment. I held a summary judgment hearing at which the parties presented intrinsic and extrinsic evidence in support of their construction of the claims in the '161, '154, and '318 patents. As a consequence, the parties placed into the record both intrinsic and extrinsic evidence in support of their claim construction positions.

The '318 patent

This patent concerns a drug formulation that allows the delivery of active drugs to the small intestine. Claim 8 of this patent includes a delivery formulation for metoprolol succinate. The "Abstract " of the '318 patent states that "[t]he present invention relates to a new oral pharmaceutical composition having an improved release of the therapeutically active compound present therein, in the lower part of the gastro-intestinal duct...."

***5** Under the heading "Background Of The Invention" the patent states that
[t]here exists an everlasting problem within pharmacy to be able to administer a therapeutically active compound as close as possible to the colon or preferably in the colon, in order to thereby to eliminate the risk of adverse influence on the active compound by the gastric juice, or to prevent irritation of the ventricular mucous membranes, or to obtain a therapeutically effect in the lower part of the gastrointestinal tract.

Under the heading "Object Of The Invention" the patent states that
[i]t has now surprisingly been shown possible to be able to solve the aforesaid problem by the present invention, which is a pharmaceutical composition in unit dosage form characterized by a core comprising a therapeutically active substance in the form of a weak base or a weak acid, on which core there is provided a first, inner layer of a diffusion membrane in the form of ethyl cellulose and/or a copolymer of polyethyl acrylate, methyl methacrylate, and trimethylammonium ethyl methacrylate chloride, and or which inner layer there is provided a second layer of at least one anionic polymer and/or fatty acid having a pk suba of 4.5 to 7, preferably 6 to 6.5.

In the "Detailed Description Of The Invention" section the patent states that
[b]y means of the present invention the core is protected against attack by gastric juice after ingestion by means of the outer layer comprising an anionic polymer and/or fatty acid having a pk suba of 4.5 to 7. When this outer layer has been removed by dissolution upon passage of the composition into the small intestine with its higher pH, a slow but controlled release of the therapeutically active compound from the core by diffusion through the diffusion membrane occurs due to the difference in concentrations on each side of said membrane. The release takes thereby place at such a rate that 80-90% of the therapeutically active compound has been released after 7 to 10 hrs, which means that the release can take place in a constant, pH-independent way, and thereby in a very reproducible way. (emphasis added)

Defendants argue that the '161 patent and the '154 patent are invalid for double patenting over claim 8 of the '318 patent. Because claim 8 depends from claim 7, which depends from claim 6, the starting point for claim construction is claim 6. Claim 6 is directed to oral controlled release pharmaceutical compositions with a core of the active drug, surrounded by a coating that is a diffusion membrane, and a second coating that resists dissolving in the pH of the stomach. It also specifies the materials used in each coating. Claim 6, 7 and 8 are as follows:
6. Oral pharmaceutical composition having an improved release therefrom of a therapeutically active compound therein which is soluble in gastric juice, independent of its solubility, having a core comprising the therapeutically active compound, a first inner layer coating on the core, in the form of a diffusion membrane which is a mixture of ethyl cellulose and a copolymer of polyethyl methacrylate-methyl methacrylate-trimethyl ammonium ethylmethacrylate chloride, in a weight relationship between the monomers of the copolymer of 63 to 65:31.7 to 32.3:2.5 to 5, and a second outer layer coating on the inner layer of at least one anionic polymer having a pk suba of 4.5 to 7.
***6** 7. Pharmaceutical composition according to claim 6, wherein the therapeutically active compound in the core has a solubility in the pH range 1 to 8 which exceeds 0.5 to 1 g per 100 ml.
8. Pharmaceutical composition according to claim 7, wherein the active compound is quinidine sulphate, quinidine bisulphate, quinidine gluconate, quinidine hydrochloride, metoprolol tartrate, metoprolol succinate, metoprolol fumarate, or

furosemide, 5-aminosalicylic acid, propranolol or alprenolol or a pharmaceutically acceptable salt thereof, or a mixture thereof with another weak base, weak acid, or salt thereof having a pk suba of 1 to 8.

Distilled to its essence, and pertinent to this lawsuit, claim 8 is directed to an oral pharmaceutical composition that has (i) a core that contains metoprolol succinate (or one of several other drugs), (ii) the core is surrounded by an inner coating that allows a controlled release of metoprolol succinate, and (iii) an outer coating that resists dissolving in the stomach with the goal of releasing the metoprolol succinate close to or within the colon.

The meaning of the term "improved release" in claim 6 can be interpreted from the specification which states that the goal of the invention is to release the active drug as close to the colon as possible. The specification also states that the diffuse membrane surrounding the core of metoprolol succinate acts to allow a "slow but controlled release" of the drug. Claim 8 patents a particular type of formulation to allow the slow and controlled release of metoprolol succinate in or near the colon.

The '161 patent

The '161 patent "Abstract" states that "[t]he present invention relates to metoprolol succinate, a new therapeutically active compound, and pharmaceutical preparations comprising this new compound."

Under the patent heading "Technical Field" the patent states that "[t]he object of the present invention is to obtain a therapeutically active compound intended to be released close to or within the colon, and particularly to such active compounds which are soluble in the pH range 1 to 8 " (emphasis added).

Under the heading "Description of the Present Invention" the patent states that

"[t]his compound can, in order to be administered orally be treated in accordance with the method proposed in EP-A1-0 040 590. Herein it has been proposed an oral pharmaceutical composition comprising a core containing a therapeutically active compound, which core has been coated with a layer comprising 10 to 85% by weight of an anionic polymer soluble at a pH above 5.5, and15 to 90% by weight of a water insoluble polymer selected from the group of quaternary ammonium substituted acrylic polymers.
...
When dosing the ready made product a number of discrete, coated particles/granules corresponding to a therapeutical dose unit of the actual therapeutical compound is administered.
When administering, in order to achieve a steady blood plasma level of the therapeutically active compound, a split dose unit of the therapeutically active compound provided with a coating according to the present invention can be administered together with some particles/granules which are not coated. (emphasis added)

*7 The sole claim of the '161 patent is "[a] [FN7] sustained release pharmaceutical composition comprising metoprolol succinate together with a pharmaceutically acceptable carrier."

FN7. The term "sustained release" was recently repositioned in the "claim" section of the '161 patent by the USPTO. The USPTO amended the patent to have the term follow the initial "a" in this claim sentence from following the second "a" as originally filed. The amendment was made at Astra's request.

For the purposes of their motion for summary judgment based on invalidity, Defendants agreed to the revised wording of the sole claim of the '161 patent.[FN8] Astra broadly construes the definitions of the terms used in this claim. Defendants disagree with Astra's definition of the term "sustained release. " Astra contends that sustained release means dosage forms which, "upon ingestion, released active to achieve desired blood plasma levels and

maintained relatively steady blood plasma levels for an extended period of time." (Pls.' Memo. in Opp. at 23.) Defendants assert that the term sustained release, as used in the mid 1980s by a person of ordinary skill in the art when this patent application was filed, was deemed interchangeable with the terms "extended release" and "controlled release."

> FN8. The USPTO had not yet approved Astra's request to change the location in the claim of the term sustained release when the briefing of this motion was filed.

The term "sustained release" does not appear in the specification of the '161 patent. The invention described by the specification is a core of "active," metoprolol succinate, coated by an anionic polymer with the goal of releasing metoprolol succinate close to or within the colon. The specification also states that uncoated particles/granules of metoprolol succinate may be combined with metoprolol succinate "provided with a coating according to the *present invention"* (emphasis added) to achieve a steady blood plasma level of metoprolol succinate. This last specification clearly regards the invention as the coated metoprolol succinate. It does not state that the invention is the coated metoprolol succinate combined with uncoated metoprolol succinate to achieve a steady blood plasma level. Astra contends that the invention claimed in the '161 patent is this latter construction which Astra labels "sustained release."

In support of its construction of the term "sustained release," Astra offers the affidavit of its expert Gerald S. Brenner. In paragraph 35 of his affidavit, Brenner states that one skilled in the art in the mid 1980s would "generally have considered a sustained release dosage form one that initially (upon ingestion) releases active to achieve desired blood plasma levels and maintains relatively steady blood plasma levels of the active for an extended period of time." (Pls.' Opp'n Summ. J. Ex. A) In support of this statement Brenner's affidavit refers to three documents without identifying them or vouching for their use by experts in his field as reference tools. The three documents are excerpts from what appear to be pharmaceutical texts. I presume that these are treatises used in the field of pharmacology.

The first excerpt is from Robert E. Notari, *Biopharmaceuticals and Clinical Pharmacokinetics, An Introduction* (Marcel Dekker, Inc., 3rd ed.1980). Notari discusses the term sustained release and states that

***8** "[g]eneral terms such as timed release, time release, extended action, or long-acting may or may not be meant to indicate that the formulation is a sustained release preparation. Unfortunately, there are no standard definitions or classifications. The following distinction will be used as a starting point, and later more precise terminology and definitions will be given to sustained release dosage forms."

Id. at 152. Notari then goes on to define the meaning of the terms "repeataction tablets," " sustained release dosage forms," and " prolonged-action preparations." He defines sustained action dosage forms as providing an " initial therapeutic dose that is available upon administration of the product followed by a gradual release of medication over a prolonged period of time." *Id.* He states that prolonged-action preparations provide the slow release of a drug and may differ from sustained release dosage only in that no initial dose in included in the prolonged-action formulation. *Id.*

Although Notari's definition of sustained release at first blush appears to support Astra's definition, Notari specifically notes that there were no standard definitions or classifications of dosage terms including sustained release. Rather, Notari's article was his attempt to create definitions that would presumably be adopted at some time in the future by a person skilled in the art. As a result, Notari's text does not support Astra's contention that sustained release had a specific meaning to one skilled in the art as of the effective date of the patent application. Instead, Notari's article establishes the opposite position; that in the mid 1980s there was no consistent interpretation of the term sustained release.

The second document relied on by Brenner is equivocal in supporting his definition of sustained

release. That excerpt is from Howard C. Ansel, *Introduction to Pharmaceutical Dosage Forms,* (Lea & Febiger 1969). Ansel states that
[s]ome solid dosage forms are designed to release their medication to the body for absorption rapidly and completely; other products may be designed to release the drug slowly for more prolonged drug release and sustained drug action. The latter type of dosage form is commonly referred to by a designation such as a *sustained-action, prolonged-action, sustained-release, prolonged-release, timed-release, extended-action,* or *extended-release* tablet or capsule.

Id. at 274. Ansel then states that "most" sustained-action dosages are designed so that a single dosage provides the "immediate release of an amount of the drug that promptly produces the desired therapeutic effect and gradual and continual release of other amounts of drug to maintain this level of effect over an extended period...." *Id.* Ansel uses the term "most" which indicates that his definition is not universal to all sustained-action dosages. As quoted above, Ansel notes the term sustained release was also referred to as extended release, timed release, extended action among other terms. These terms interchangeably referred to dosages, which Notari highlighted in his treatise published ten years after Ansel's, that may not be an indication of sustained release as defined by Ansel because there were still no standard definitions of any of these terms in 1980.

***9** Finally, the third treatise Brenner relies on for his definition of sustained release is *Remington's Pharmaceutical Sciences* (Mack Pub. Co., Arthur Osol ed.1980). That treatise states that long-acting oral products have been described by a variety of terms. *Id.* at 1596. The treatise then proposes classifying long-acting products into the following three types: sustained release, prolonged release, and repeat action. *Id.* This treatise does not state that sustained release is defined similarly by those skilled in the art. To the contrary, it offers a definition that may be adopted at some time in the future by those skilled in the art.

The three treatises relied on by Astra and its expert Brenner are consistent only in that none of the treatises state that sustained release had a uniform definition used by those skilled in the art in the mid 1980s. At best these treatises offer definitions which may or may not have been uniformly adopted. What is clear is that sustained, extended, or timed release dosages were deemed to be dosages that released more slowly over time than immediate release dosages.

The prosecution history of the '161 patent also demonstrates that Astra's own definition of sustained release was not consistently maintained during the prosecution of the patent. As previously noted, the term sustained release does not appear in the specification of the patent. When originally filed, the claims of the patent were directed to metoprolol succinate and a "pharmaceutical composition, characterized in that the active compound is metoprolol succinate." (Defs.' Ex. Q at 145) The USPTO examiner rejected these claims as obvious over prior art. *Id.* at 167-169. Hassle (Astra) responded to the rejection with a declaration of Dr. John Anders Sandberg. Hassle represented that Sandberg's declaration showed that metoprolol succinate was "useful as a sustained release form of metoprolol." *Id.* at 174. Sandberg's declaration interchangeably used the terms extended release, sustained release, and controlled release in supporting the selection of metoprolol succinate. *Id.* at 181, 184, and 189. The examiner agreed to issue the '161 patent if the term sustained release was inserted into the claim. In his deposition for this case, Sandberg stated that he thought that controlled release, sustained release, and extended release dosages were essentially the same. (Defs.' Ex. V at 413) One of the named inventors of the '161 and '154 patents, Curt Appelgren, stated in his deposition that in 1983 the terms controlled release, extended release, and sustained release were use interchangeably. The other named inventor of the " 161 and '154 patents, Eva Christina Eskilsson, stated in her deposition that sustained release could be the same as extended release, which could be a dosage form completely releasing an active drug from "one to many hours." (Defs.' Ex. T at 345)

Defendants have placed more treatises and articles into the record that state that sustained release, prolonged action, controlled release, extended

action, and time release were all used interchangeably to describe preparations that release a drug over an extended period of time. (Defs.' Exs. AB, AC, and AD)

***10** Astra itself uses the term "extended release" in their Complaints and various pleadings when they describe their drug Toprol-XL® which is the subject of this infringement action.

Based on the lack of a definition of sustained release in the '161 patent, the specification's statement that the "object of the present invention is to obtain a therapeutically active compound *intended to be released close to or within the colon"* and the extrinsic evidence offered by the parties, I conclude that sustained release simply refers to a dosage that is distinguished from immediate release in that it releases metoprolol succinate over a controlled or extended period of time close to or within the colon. Astra's definition requiring an immediate release is not supported by the specification. Astra's extrinsic evidence in the form of Brenner's affidavit "is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history" and is discounted. *Phillips,* 425 F.3d 1318. In addition, Brenner's definition is not even supported by the treatises he relies on in support of his position.

The specification itself states that if a steady blood plasma level of the therapeutically active compound is desired, an optional formulation of uncoated metoprolol succinate can be combined with metoprolol succinate with a coating according to the present invention. That statement, read in context of the entire patent, indicates that the invention of the '161 patent is a coated forms of metoprolol succinate that provides for a controlled or extended release of the drug; it is not a pharmaceutical composition that includes an immediate release of metoprolol succinate as Astra would define the term sustained release.

The '154 patent

The only claim in the '154 patent is "metoprolol succinate." The invention is the composition itself.

Comparing the claims

Claim 8 of the '318 patent is directed to a specific type of controlled release formulation of metoprolol succinate. The claim describes a metoprolol succinate core surrounded by two coatings (an inner diffuse membrane that allows a slow but controlled release of active and an outer coating that resists stomach acid so that the active can release near or in the colon).

The claim of the '161 patent is directed to coated forms of metoprolol succinate that are designed to have a controlled release of the metoprolol succinate (the active) near or in the colon. The claim does not limit the method or structure by which controlled release is achieved. It is broadly directed to formulations that would provide a controlled release of metoprolol succinate near or in the colon.

Defendants argue that claim 8 of the '318 patent is a particular type of a controlled release formulation of metoprolol succinate and that the claim of the '161 patent is a broad claim to any controlled release formulations of metoprolol succinate. Defendants assert that the relationship between the claim 8 of the '318 patent and the claim of the '161 patent is that of "species and genus," that is, the former discloses a specific embodiment within the latter's general scope.

***11** A species/genus relationship is a form of double patenting wherein the second broader claim is deemed invalid because it is anticipated by, and therefore not patently distinct from, an earlier species claim. *See In re Goodman,* 11 F.3d 1046, 1053 (Fed.Cir.1993); *Eli Lilly & Co. v. Barr Labs., Inc.,* 251 F.3d 955, 971 (Fed.Cir.2001); *Geneva Pharmaceuticals, Inc. v. GalaxoSmithKline PLC,* 349 F.3d 1373, 1383 (Fed.Cir.2003).

Astra asserts that the relationship between claim 8 of the '318 patent and the claims of the '161 patent and the '154 patent should be viewed as that of combination/element which does not implicate the

doctrine of double patenting. *See In re Allen,* 52 C.C.P.A. 1315, 343 F.2d 482, 486 (C.C.P.A.1965); *In re Heinle,* 52 C.C.P.A. 1164, 342 F.2d 1001 (C.C.P.A.1965). Astra contends that the claims of the '161 patent and the '154 patent are independent elements of the combination claim of claim 8 of the '318 patent. Astra argues that metoprolol succinate was not a necessary element to the combination claim 8 of the '318 patent and that metoprolol succinate has utility by itself or in other combinations. As a result, Astra argues, its claims concerning metoprolol succinate cannot be invalidated for double patenting.

However, " '[i]n situations in which an element or subcombination issues after the combination, the matter should be analyzed as one of a generic claim issuing after a later filed specific or improvement claim." ' *In re Emert,* 124 F.3d 1458, 1462 (Fed.Cir.1997)(quoting 3 Donald S. Chisum, *Chisum on Patents* § 9.03[2][b][iii]).

That is the situation in the present case. Even if the '161 claim and the '154 claims are classified as elements, they issued after the combination claim of claim 8 of the '318 patent issued. It is therefore appropriate to analyze these claims as a species/genus relationship. I find that claim 8 of the '318 patent is a particular type of a controlled release formulation of metoprolol succinate and that the claim of the '161 patent is a broad generalized claim to controlled release formulations of metoprolol succinate. Because the earlier issued claim 8 of the '318 patent is a species of the later issued genus claim of the '161 patent, the '161 claim is invalid for obviousness type double patenting.

The sole claim of the '154 patent is "metoprolol succinate." Such a claim encompasses any formulation that uses this chemical composition without limitation. Claim 8 of the '318 patent is directed to certain pharmaceutical compositions containing metoprolol succinate. The '154 patent broadly claims any pharmaceutical compositions containing metoprolol succinate. The relationship between these claims is that of species/genus. The '154 patent is a genus of the species claimed in the '318 patent. Consequently, the claim of the '154 patent is anticipated by claim 8 of the '318 patent and is void for double patenting because it is not patently distinct form claim 8 of the '318 patent.

***12** If the '161 and '154 patents were valid, they would prevent the public from using the earlier issued invention of claim 8 of the '318 patent upon its expiration because they completely encompass claim 8 as to metoprolol succinate. Such a result would defeat the public policy behind the double patenting doctrine which is to allow the public to freely use a patent upon its expiration.

As a result, I find by clear and convincing evidence that the '161 patent and the '154 patent are invalid on the basis of double patenting over claim 8 of the '318 patent.

Terminal disclaimers

Defendants also asserted that the '161 and '154 patents are invalid for double patenting over earlier issued patent United States Patent 4,957,745 (the '745 patent); and that the '154 patent is invalid for double patenting over the '161 patent.

Claim 7 of the '745 patent is another controlled release formulation of metoprolol succinate. It claims a formulation of metoprolol succinate wherein the metoprolol is released through a coating over a period of at least fifteen hours. Base on the same analysis applied to claim 8 of the '318 patent, I find that claim 7 of the '745 patent is a species of the later filed genus in the claims of the '161 and '154 patents. The claim of the '161 patent and '154 patent would be invalid for double patenting over claim 7 of the '745 patent if not for the question of terminal disclaimers.

By the same analysis the claim of the '154 patent would also be invalid for double patenting over the '161 patent.

However, Astra filed terminal disclaimers under 35 U.S.C. § 253 as to the '161 patent and the '154 so that they expire at the same time that the '745 patent expires.[FN9] Astra contends that these terminal disclaimers cure any double patenting issues that may have arose between the '154 patent and the '161

patent and those two patents and the '745 patent.

FN9. Defendants state that the expiration date of the '745 patent is September 18, 2007.

Defendants argue that the terminal disclaimers should have been made while the '161 and '154 patents were being prosecuted. Defendants assert that Astra's disclaimers, filed years after the patents have issued, are ineffective based on public policy. Defendants contend that a listing of pharmaceutical patents and their expiration dates in the Orange Book [FN10] deters others from competing with the patent holder on those patents. Defendants assert that allowing a patent holder to avoid a double patenting litigation by filing a terminal disclaimer years after a patent was issued gives the patentee an unfair advantage by suppressing competition.

FN10. The United States Food & Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, commonly referred to as "the Orange Book," is a register that provides notice of patents covering name brand drugs.

The terminal disclaimer statute doe not set a time limit to file a disclaimer. The language of the statute clearly contemplates that a disclaimer can be filed by a patentee regarding a patent that has already issued. 35 U.S.C. § 253 ("patentee ... may disclaim .. . the entire term, or any terminal part of the term, of the patent granted...."). The United States Court of Appeals for the Federal Circuit has recently confirmed that a terminal disclaimer may be filed after a patent is issued. *Perricone v. Medicis Pharmaceutical Corp.,* 432 F.3d 1368, 2005 WL 3468126, at *5 (Fed.Cir. December 20, 2005). The *Perricone* opinion also states that a "terminal disclaimer can indeed supplant a finding of invalidity for double patenting." *Id.* The opinion strongly infers that a terminal disclaimer filed years after a judicial finding of invalidity can reinstate the validity of the patent. *Id.* The court in *Perricone* did not raise concerns that equity or public policy should prevent terminal disclaimers from being effective if filed years after a patent has issued.

***13** Based on the language of the terminal disclaimer statute and the opinion in *Perricone,* I find that Astra's terminal disclaimers of the '161 patent and the '154 patent effectively avoids a finding of double patenting of those patents over the '745 patent and the '154 patent over the '161 patent.

The '161 patent not entitled to priority and is therefore invalid as anticipated

Defendants also argue that the '161 invalid as anticipated by prior art under 35 U.S.C. § 102(b). Defendants contend that the '161 patent was not entitled to priority to the '318 patent application. Through the use of priority, its possible for a patentee to avoid the consequences of any prior art which existed before his present patent application was filed. That is because a priority entitles the patentee to adopt the earlier filing date of a related patent application.

The '161 patent issued from a continuation-in-part patent application filed in March 1988. The application claimed priority to the United States application for the '318 patent which was filed on January 10, 1985 (the '318 patent application in turn claimed priority to the Swedish patent application (SE 8400085) filed on January 10, 1984). If the '161 patent is not entitled to priority to the '318 patent application, its effective filing date would be March 1988. Any references with sustained release metoprolol succinate formulations that existed before March 1988 might qualify as prior art that anticipates the '161 patent.

Patent law allows a patent applicant to claim priority to an earlier filed patent application. 35 U.S.C. § 120. For a claim in a later-filed application to be entitled to the filing date of an earlier application under section 120, the earlier application must comply with the written description requirement of paragraph one of 35 U.S.C. § 112. *Tronzo v. Biomet, Inc.,* 156 F.3d 1154, 1158 (Fed.Cir.1998).

Paragraph 1 of section 112 requires that the specification "contain a written description of the invention, and of the manner and process of making and using it." To meet this requirement, "the disclosure of the earlier application, the parent, must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the parent application was filed." *Id.* (citations omitted.) A disclosure in a parent application that "merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations." *Id.* (citation omitted).

As previously discussed, the '318 patent is directed to, in pertinent part, a specific type of controlled release formulation of metoprolol succinate. The claim describes a metoprolol succinate core surrounded by two specified coatings (an inner diffuse membrane that allows a slow but controlled release of active and an outer coating that resists stomach acid so that the active can release near or in the colon). The specification of the '318 patent is limited to this dual-coating system. The specification does not describe other systems for the sustained release of metoprolol succinate.

***14** The '161 patent broadly claims sustained release formulations of metoprolol succinate with little, if any, limitation. The specification of the '318 patent does not reasonably convey to one of skill in the art that the inventor of the '318 patent possessed the subject matter of the '161 patent at the time the '318 application was filed. To be entitled to a priority the disclosure in the '318 patent must describe the '161 patent invention with all its limitations. The '318 patent does not contain this information.

Because the specification of the '318 patent does not meet the written description requirement of invention of the '161 patent, the '161 patent is not entitled to priority to the '318 patent. As a result, the effective filing date of the '161 patent is March 25, 1988.

Swedish patent application SE 8400085 is the parent of the '318 patent and the grandparent of the '161 patent. The Swedish application published on July 17, 1985. The Swedish application discloses, among other things, the species of sustained release metoprolol succinate that becomes claim 8 of the '318 patent. The disclosure of the species in Swedish patent anticipates the genus of sustained release metoprolol succinate which is the invention of the '161 patent. Because the species in the Swedish patent application was published (July 1985) more than one year before the '161 patent application was filed (March 1988), the '161 patent is invalid under 35 U.S.C. § 102(b) (a person is entitled to a patent unless the invention was described in a printed publication more than one year before the patent application was filed in the United States).

Similarly, as already discussed, the '745 patent and the '161 patent have a species/genus relationship. The '745 patent was filed in September 1986. An issued United States patent qualifies as prior art as of its filing date. 35 U.S.C. § 102(e). Because the '745 patent application was filed more than one year before the '161 patent application, the '745 patent is prior art which anticipates the '161 patent and renders it invalid.

As a result, I find by clear and convincing evidence that the '161 patent is not entitled to priority to the '318 patent and that the '161 patent is invalid as anticipated by the publication of the Swedish patent application and the filing of the '745 patent application.

Unenforceablility based on inequitable conduct

For more that three years, from October 1985 through the late fall of 1988, Astra and a competitor named Lejus Medical contested the issue of who invented metoprolol succinate. This dispute was uncovered during discovery in this lawsuit. Astra never revealed its inventorship dispute with Lejus to the USPTO during the prosecution of the patents in suit. Astra's failure to disclose this long-running inventorship dispute is one basis for Defendants' motion for summary judgment for inequitable conduct.

Defendants also assert that Astra intentionally did not name the correct inventors in Astra's prosecution of the patents in suit. Curt Appelgren and Eva Eskilsson are the two named inventors of the '161 patent and the '154 patent. Defendants assert that Appelgren and Eskilsson are not the inventors of the patents in suit and that listing them as the named inventors on the patent applications was a material misrepresentation to the USPTO.

***15** Defendants contend that Astra's naming the wrong inventors on the patents and Astra's failure to disclose to the USPTO the inventorship dispute each independently constitute an act of inequitable conduct which render the patents in suit unenforceable.

Astra denies these allegations. It asserts that it named the correct inventors of the '161 and the '154 patents. Astra also contends that, through its United States patent counsel, it fully satisfied its duties of candor and disclosure to the USPTO during the prosecution of these patents.

Standard regarding inequitable conduct

"Inequitable conduct includes affirmative misrepresentations of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1318 (Fed.Cir.2000) (citation omitted). Because the defense of inequitable conduct is entirely equitable in nature, it is an issue for the court and not a jury to decide. *Id.*

To determine whether inequitable conduct exists requires the trial court to determine whether the conduct meets a threshold level of materiality and whether the evidence shows a threshold level of intent to mislead the USPTO. *Id.* at 1318-19. Materiality and intent must be established with clear and convincing evidence. *Frazier v. Roessel Cine Photo Tech, Inc.*, 417 F.3d 1230, 1234 (Fed.Cir.2005). Once threshold levels are established, the trial court is required to weigh materiality and intent. *PerSeptive Biosystems, Inc.*, 225 F.3d 1319. "The more material the conduct, the less evidence of intent will be required in order to find that inequitable conduct has occurred." *Id.* (citation omitted). In "the absence of a credible explanation, intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information." *Bruno Indep. Living Aids, Inc. v. Acom Mobility Services, Ltd.*, 394 F.3d 1348, 1354 (Fed.Cir.2005). After weighing materiality and intent, the court must then determine whether the applicant's conduct is so culpable that the patent should be held unenforceable. *PerSeptive Biosystems, Inc.*, 225 F.3d 1319. Defendants assert that Astra engaged in inequitable conduct towards the USPTO by (1) misrepresenting the inventors of the '161 patent and the '154 patent, and (2) failing to disclose the inventorship dispute between Astra [FN11] and it competitor Lejus.[FN12] Defendants argue that this information about inventorship was material to the prosecution of the patents.

FN11. This dispute was actually between Hassle and Lejus. Hassle is now part of AstraZeneca and I will use the term "Astra" to refer to both Hassle and Astra as the parties have done in their briefs.

FN12. Defendants' allegations of inequitable conduct arose from information uncovered in discovery concerning who originally conceived and synthesized metoprolol succinate and a dispute over inventorship of that compound.

Information is material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. *Id.* at 1322 (quotations and citations omitted). Because it is a critical requirement for obtaining a patent, the issue of inventorship is highly material in the patent prosecution process. *Id.* at 1321; 35 U.S.C. § 102(f) (A person shall be entitled to a patent unless he did not himself invent the subject matter sought to be patented.). In turn, conduct that would mislead the USPTO as to the identity of the true inventors of a patent or conduct that fails to disclose information

about a dispute concerning inventorship would be highly material to the question of inequitable conduct because of the patentee's duty of candor and disclosure. *See* 37 C.F.R. § 1.56 ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.").

***16** Disputes concerning inventorship are material information that need to be disclosed. *PerSeptive Biosystems, Inc.,* 225 F.3d at 1321 (citing Manual of Patent Examining Procedure § 2001.06(c) and § 2004). Because conduct concerning inventorship is so highly material, less evidence of intent is required in order to find that inequitable conduct has occurred.

Inventorship of metoprolol succinate

The compound metoprolol was invented in the 1960's by Hassle, at the time, a Swedish pharmaceutical research and development company located in Mölndal, Sweden. Metoprolol was discovered to be very useful in treating heart disease. Astra (Hassle) began work to develop a commercial metoprolol product. Astra investigated various salts of metoprolol to be used in a drug formulation. It is undisputed that in 1971, an Astra chemist named Toivo Nitenberg synthesized metoprolol succinate as well as the tartrate and sulfate salts of metoprolol. Nitenberg recorded the synthesis of these salts in his lab notebook. The tartrate salt was chosen for commercialization and became Astra's product known as Lopressor.

In the 1980's Astra perceived a need for a once-daily dosing formulation of metoprolol. Because this goal could not be effectively achieved with metoprolol tartrate, Astra formed a research group to develop an extended release form of metoprolol. Curt Appelgren and Eva Eskilsson were part of that group.

In 1982, Appelgren and his colleague Ulf Jonsson went to Astra's facility in Södertälje, Sweden and asked chemists there to form some metoprolol salts with a lower solubility than the tartrate for evaluation as an extended release form of metoprolol. They met with Urban Stenhede, a chemist and head of the research department. Jonsson (Astra's Rule 30(b)(6) witness) [FN13] testified in his deposition that he and Appelgren asked Stenhede to make some salts of metoprolol, other than the tartrate, with lower solubility. Jonsson testified that there was no specific request made to Stenhede to make metoprolol succinate.

FN13. A Rule 30(b)(6) witness must be able to gives binding answers on a corporation's behalf. *Reilly v. Natwest Markets Group Inc.,* 181 F.3d 253, 268 (2nd Cir.1999).

In Appelgren's deposition, when asked about his and Jonsson's meeting with Stenhede, Appelgren could not recall specific details of the meeting. He did not testify that he gave Stenhede a list of salts to make, including metoprolol succinate. But in his later filed declaration submitted in opposition to summary judgment on the issue of inequitable conduct, dated ten months after his deposition, Appelgren states that he did give Stenhede a list of salts to make that included metoprolol succinate. No such list was produced in discovery.

Stenhede, in turn asked chemist Lars Lilljequist to form salts of metoprolol with a lower solubility than the tartrate salt. Lilljequist is the person who actually synthesized metoprolol succinate. In his deposition, Lilljequist did not recall who suggested which salts of metoprolol to form nor could he recall if he was given a list of salts to make. Yet he clearly testified that no one specified which acids to use to make the salts (specifying the acids to use would be another way of specifying which salt to form). (Def. Andrx's Memo in Reply Ex. 3 at 87) But in his later filed declaration submitted in opposition to summary judgment, dated seven months after his deposition, Lilljequist states that he received a list of salts to make that included metoprolol succinate.

***17** In their depositions, both Appelgren and

Eskilsson testified that they were unaware that Nitenberg had formed metoprolol succinate at their company in 1971. They testified that they had never seen his lab book entry showing the formation of that salt. In her deposition, Eskilsson states that she did not recall asking anyone to make metoprolol succinate and that she never made metoprolol succinate. She also did not recall why she was a named inventor of metoprolol succinate in United States Patent Application No. 172,897 (the application that became the '161 patent and through a continuation the '154 patent). (Defs. Memo in Supp. Ex. 16 at 496) However, in her later filed declaration submitted in opposition to summary judgment, dated ten months after her deposition, she asserts that she did invent metoprolol succinate and the basis for that belief.

In December 1982, Appelgren left Astra to found Lejus Medical, a Swedish pharmaceutical research and development company. A few months later Eskilsson also became employed at Lejus.

On January 10, 1984, Lejus filed a patent application (SE 8400085) with the Swedish Patent Office. That application published as EP 148811 on July 17, 1985. The Swedish patent application was for delayed and extended release dosage forms of pharmaceutical compositions, including metoprolol succinate. Appelgren and Eskilsson are listed as the named inventors.

On January 1, 1985, the same application was filed in the United States as United States Application No. 690,197 which issued on October 25, 1988, as the '318 patent discussed above. The '318 patent is the parent and grandparent of the patents in suit, the 161 patent and the '154 patent, respectively.

When the Swedish patent application published in July 1985 it was noticed by Astra. Astra believed that metoprolol succinate had been invented by its employee Toivo Nitenberg and that extended release dosage formulations of metoprolol succinate were also Astra's invention. In an internal memorandum dated September 19, 1985, Astra's in-house counsel, Bengt Wurm, stated that it appeared Lejus was trying to appropriate Astra's claim to metoprolol succinate and extended release dosage formulations of metoprolol succinate. Wurm warned that "the important principle is that the use of metoprolol succinate became known because Lejus' [published] application was generally available on July [17], 1985, and therefore can be cited as a novelty reference with respect to later applications that concern preparations containing substances such as metoprolol succinate." (Defs.' Memo in Supp. Ex. 10) In other words, the publication could constitute potentially invalidating prior art of any subsequent Astra application seeking to patent metoprolol succinate.

On October 21, 1985, Astra filed an action in the Swedish Patent Office to transfer the metoprolol succinate inventions of the Lejus' Swedish application to Astra. Astra's petition, signed by Astra's in house counsel Wurm, asserted that metoprolol succinate had *not* been invented by Appelgren or Eskilsson, but rather it had been invented by an Astra chemist named Toivo Nitenberg. (Defs.' Memo in Supp. Ex. 11) In 1985, Astra's petition at the Swedish Patent Office noted that Appelgren and Eskilsson merely "worked with preparations for controlled release of the compound invented by Toivo Nitenberg." *Id.* In making this assertion, Wurm relied on information from John Sjogren, the head of the formulation department at Astra. (Defs.' Memo in Supp. Ex. 12)

***18** Wurm advised Astra, however, that seeking transfer of the metoprolol succinate invention under Swedish patent law could be time consuming, expensive, uncertain and of questionable future value because the Lejus publication could be cited as prior art to "later applications that concern preparations containing substances such as metoprolol succinate." (Defs.' Memo in Supp. Ex. 10)

As an alternative to pursing its action in the Swedish Patent Office, Astra attempted to reach an accommodation with Lejus. In the fall of 1985, Astra approached Lejus and asserted that metoprolol succinate (and its pharmaceutical compositions) had not been invented by Appelgren and Eskilsson but had, in fact, been invented by Nitenberg at Astra. Lejus did not dispute Astra's claim. Lejus agreed to file new patent applications

on the metoprolol succinate inventions (to be carved from the 1984 Swedish patent application and each of its foreign counterparts, e.g. the '318 patent application) and then assign these applications to Astra. In exchange Astra agreed to withdraw its ownership claim with the Swedish Patent Office claiming that Toivo Nitenberg was the actual and sole inventor of metoprolol succinate. In April 1986, Astra and Lejus entered a written agreement incorporating these terms.

Prior to the signing of the formal agreement, Lejus had already filed, in January 1986, the required new application in Sweden on the metoprolol succinate inventions (Swedish Patent Application No. 8600202-9).

Wurm was succeeded by Rune Nasman as Astra's in-house attorney. On February 12, 1988, almost two years after Astra and Lejus entered the agreement regarding the metoprolol inventions, Nasman wrote two letters to Lejus' outside patent agent Ulf Inger still asserting that Toivo Nitenberg was the sole inventor of metoprolol succinate. In the first letter, entitled "Metoprolol succinate-divided application in the United States," Nasman reasserts Astra's position that Toivo Nitenberg was *the* inventor of metoprolol succinate ("As we understand it, and as was stated in the objection to the Swedish Patent Office, *the inventor is Toivo Nitenberg,* employed by Hassle.") (emphasis added) (Defs.' Memo in Supp. Ex. 23)

In the second letter of February 12th, entitled " Swedish patent application 8600202-9, AB Hassle," Nasman tells Inger that Toivo Nitenberg should be named as the inventor of metoprolol succinate. He states that Appelgren and Eskilsson can remain as co-inventors with Nitenberg because the application also "pertains to a pharmaceutical composition, and Appelgren and Eskilsson appear to have invented a special form of pharmaceutical composition under this patent claim." (Defs.' Memo in Supp. Ex. 24)

On March 25, 1988, a little over a month after Nasman sent these letters, Lejus filed United States Patent Application No. 172,897 (which became the '161 patent). This application was the United States counterpart to the Swedish Application No. 8600202-9 discussed in Nasman's letters. Like its Swedish counterpart, the United States application claimed: 1) metoprolol succinate and 2) "a pharmaceutical composition, characterized in that the active compound is metoprolol succinate." The named inventors were Appelgren and Eskilsson. The application was filed as a continuation-in-part of United States Patent Application No. 690,197 (which became the '318 patent). By filing the application as a continuation-in-part of the '197 application and naming the same inventors, the '897 application was entitled to priority to the earlier filing date of the '197 application, January 10, 1985. A material benefit of the January 10, 1985, filing date would be to avoid a potential hurdle of prior art revealed in the publication of EP 148811 on July 17, 1985. The issue of a potential prior art problem had been specifically identified by Wurm two and a half years earlier in his September 19, 1985 internal memorandum at Astra.

***19** On May 31, 1988, *two months after* the '897 application is filed in the United States, Nasman writes another letter to Inger stating that he looks forward to Lejus' assignment of the European and United States metoprolol succinate patent applications to Astra per their agreement. Nasman again reemphasizes Astra's desire for Nitenberg to be named as the inventor of metoprolol succinate because *"[t]here can be no doubt* that the invention as specified in claim 1 was made in connection with Toivo Nitenberg's synthesis of the salt." (emphasis added) (Defs. Memo in Supp. Ex. 25.) He further states that Appelgren's and Eskilsson's roles as inventors to claim 2 (a generally specified pharmaceutical composition of metoprolol succinate) "should be limited to the special form of pharmaceutical composition that is specified in Lejus' original application." *Id.*

In late 1988, the prosecution of the '897 patent application was transferred from Lejus' United States patent counsel to Astra's United States patent counsel, Edward Filardi. On January 9, 1989, Nasman wrote to Filardi for advice with respect to inventorship, which Nasman described as an *"open question"* with respect to the '897 application. (emphasis added) (Defs. Memo in Supp. Ex. 27) His letter states, in pertinent part, as follows:

The background, to my knowledge, is that metoprolol [succinate] was first synthesized on September 6, 1971 by the Hassel chemist Toivo Nitenberg. I enclose a copy of Mr. Nittenberg's lab protocol of the synthesis (in Swedish).
In 1985 we discovered that a Swedish patent application (no. 8400085-0) filed by Lejus Medical AB and naming two former Hassle employees, Kurt Appelgren and Christina Eskilsson, mentioned metoprolol succinate as an active component for an invented pharmaceutical composition. Hassle took action against Lejus in the Swedish patent office asserting rights under the patent based on Hassle's view that the invention of metoprolol succinate was made by Mr. Nitenberg and that Appelgren and Eskilsson had used secret Hassle know-how in making reference to metoprolol succinate in the Lejus patent application. After negotiations between the parties a settlement was reached stipulating inter alia that Lejus w[as] to divide out the parts of their applications pertaining to metoprolol succinate into separate applications, which were to be assigned to Hassle, and that Hassle w[as] to withdraw all actions for rights under the patents.
As I understand it, there remains an open question who is the proper inventor of the invention claimed in the instant U.S. patent application [the '161 patent application], and your advice on this would be appreciated. I may inform you that we have [u]nofficially proposed to Lejus, via Ulf Inger, to add Mr. Nitenberg as an inventor in the Swedish counterpart to the instant application, but so far Lejus h[as] not agreed to do this.

Id. The letter does not inform Filardi that Astra also sought to have Lejus name Nitenberg as the inventor of metoprolol succinate in the United States patent applications. *See* Nasman's letters to Inger above.

***20** On January 10, 1989, Filardi sent a letter to Nasman stating that he discussed the inventorship issue with Peder Berntsson and Gerhard Miksche but had several questions that could not be resolved. (Defs.' Memo in Supp. Ex. 28) Filardi proposed that he call Nasman the next day, January 11, 1989, with Berntsson and Miksche participating in the call, to discuss the issue further.

The call was made on January 11th. Nasman writes a letter to Filardi the same day referring to patent application '897 (and two other applications). (Defs.' Memo in Supp. Ex. 29) The letter refers to " the very useful telephone conversation today with you." Berntsson, Miksche, and a Margareta Linderoth also participated in the call. The issue of inventorship is not mentioned in the letter. This letter ends the paper trial of how the open question of inventorship was addressed by Nasman and Filardi.

On April 19, 2005, Filardi was deposed for this lawsuit. He was asked if he reviewed documents in preparation of his deposition. He said that he had and that some of the documents helped refresh his recollection of what occurred during the prosecution of the patent applications as issue. He testified that he could not recall anything that was said during the January 11, 1989 telephone call with Nasman. He specifically states that he could not recall anything that was said about the inventorship of the '897 application. He could not recall if he did, or did not, render any opinion regarding inventorship of the '897 application during the phone call. Aside from Nasman's January 11th letter, the record does not contain any other contemporaneous evidence of Filardi's advice regarding the "open question" of inventorship raised by Nasman.

Astra states that Peder Berntsson was Nitenberg's boss at Astra and was very familiar with Nitenberg's synthesis of metoprolol succinate. Berntsson met with Filardi on January 10th and was involved in the conversations between Nasman and Filardi on January 11th. However, there is no evidence in the record of what Berntsson specifically discussed with Filardi on January 10th and 11th. Berntsson has submitted a declaration in opposition to summary judgment on the issue of inequitable conduct. Berntsson's declaration does not mention these meetings with Filardi. Nor does it reveal that he ever provided any information to Filardi or Nasman about inventorship of metoprolol succinate.

According to Astra's memorandum in opposition to summary judgment:
During the January 11 telephone call, Filardi

advised Nasman with the requested legal advice on inventorship. In particular, Filardi advised Nasman that, in his opinion, Nitenberg was not an inventor or co-inventor of metoprolol succinate, that there was no doubt about it, that none of the information set forth in Nasman's letter to Filardi was material, and that, therefore, the information did not need to be disclosed to the USPTO.

(Pls.' Memo in Opp. at 20) Astra cites to the declarations of Nasman and Filardi in support of this assertion.

***21** Astra's assertion of what was discussed during the January 11th phone call is not supported by the record in this case. In his deposition, Filardi stated that he had no recollection of what was discussed about inventorship in his conversation with Nasman on January 11th. Filardi made a declaration, however, three months after his deposition which has been submitted in opposition to summary judgment. In pertinent part of his declaration concerning the inventorship issue, Filardi does not state that he recalls what happened but rather what is "clear" to him based on review of some documents. In other words, Filardi still does not recall the relevant conversation. Filardi never declares what he actually knew, considered or said. His declaration reflects that he is surmising or guessing at what he must have told Nasman.

For example he states that based on the contemporaneous documents:
it is clear that I considered the five items of information provided to me by Mr. Nasman and consulted with a senior Astra scientist who knew Mr. Nitenberg; I concluded that, under U.S. law, Mr. Nitenberg was not an inventor.
it is clear to me that I gave an opinion to Mr. Nasman that Mr. Nitenberg was not an inventor
it is clear to me that I concluded that the information provided to me by Mr. Nasman, including the assertions he had made to Lejus that he considered Nitenberg to be an inventor under Swedish law, were not "material" under Rule 56 and need not be disclosed to the USPTO.

(emphasis added) (Declar. of Filardi ¶ 10) Also, "I believe that I discussed the question of inventorship with Astra's Peder Berntsson and Astra's Gerhard Miksche, both of whom happened to be in my New York City offices on another Astra matter." (Declar. of Filardi ¶ 12) These are not recollections of what happened but rather are a guess of what must have of happened in Filardi's opinion. I find that this declaration contradicts Filardi's deposition testimony about his recall of events and should be discounted. *See Dotson v. Delta Consol. Industries, Inc.*, 251 F.3d 780, 781 (8th Cir.2001) (a party may not create a question of material fact, and thus forestall summary judgment, by submitting an affidavit contradicting his own sworn statements in a deposition).[FN14]

FN14. I note here that Astra has maintained a pattern of submitting witness declarations that contradict their own deposition testimony. For example, compare Appelgren's deposition testimony that he could not recall the particulars of his meeting with Stenhede in Södertälje with his post-deposition declaration that he provided a list of salts to make which included metoprolol succinate. This declaration contradicts not only Appelgren's deposition responses but also the deposition of Astra's Rule 30(b)(6) witness, Ulf Jonsson, who stated that when he and Appelgren met with Stenhede they did not specifically direct him to make metoprolol succinate. A party cannot avoid summary judgment by filing a declaration that contradicts that party's Rule 30(b)(6) deposition testimony. *See Rainey v. American Forest and Paper Ass'n, Inc.*, 26 F.Supp.2d 82, 95 (D.D.C.1998). In his deposition, Lilljequist did not recall who suggested which salts of metoprolol nor could he recall if he was given a list of salts to make. Yet he clearly stated that no one specified which acids to use to make the salts (specifying the acids to use would be another way of specifying which salt to form). Yet in his post-deposition declaration he states that he did receive a list of salts to make that included metoprolol succinate. Similarly, in her

> deposition Eskilsson could not recall why she was a named inventor of metoprolol succinate. Yet in her post-deposition declaration she asserts that she did invent metoprolol succinate and the basis for her belief.

Even if I were to ignore Filardi's deposition testimony and I were to rely solely on Filardi's declaration, Filardi's conclusion that "there was no inventorship issue for the USPTO to decide" (Declar. of Filardi ¶ 12) is flawed because it is undisputed that Filardi was not provided with all of the facts or documents regarding the inventorship dispute. Two assumptions made by Filardi in his declaration highlight the lack of full disclosure made by Astra to Filardi which materially prevented Filardi from being fully apprised of the inventorship dispute.

The first assumption concerns the question of what Filardi was told about the inventorship dispute with Lejus regarding Appelgren and Eskilsson. In his declaration, Filardi states that he "does not recall being aware of *any information* that called into question whether Appelgren and Eskilsson were the true and correct inventors." (emphasis added) And that *"the only question raised by Astra* was whether, under U.S. law, Nitenberg should be *added* as an additional inventor ...." (emphasis added) (Declar. of Filardi ¶ 10)

***22** The reason that Filardi's is not able to recall " any information that called into question" Appelgren's and Eskilsson's roles as inventors is that it is undisputed that Astra never gave Filardi copies of Nasman's letters to Ulf Inger dated February 12, 1988 and May 31, 1988. Astra's contention that Appelgren and Eskilsson did not invent metoprolol succinate was the subject of a long-running dispute between Astra and Lejus. As discussed above, Nasman's letters clearly assert that Nitenberg is *the* inventor of metoprolol succinate and that Appelgren's and Eskilsson's inventorship " *should be limited* to the special form of pharmaceutical composition that is specified in Lejus' original application" which was claim 2 of the Swedish and United States applications. (emphasis added)

In adition, Astra initiated an action in the Swedish Patent Office asserting that Nitenberg was true inventor of metoprolol succinate and that Appelgren and Eskilsson merely "worked with preparations for controlled release of the compound invented by Toivo Nitenberg." (Defs.' Memo in Supp Ex. 11) It is undisputed that Astra did not give Filardi a copy of the Swedish Patent Office submission filed by Astra contesting the Lejus patent based on the dispute over inventorship. It is also undisputed that Astra did not provide Filardi with a copy of the agreement reached between Astra and Lejus regarding dividing up the patents.

Based on Filardi's "recollection" of events, it is apparent that he was not told the whole story of the long-running dispute between Astra and Lejus concerning who invented metoprolol succinate. Because Filardi "had no information that would cause [him] to question whether Appelgren and Eskilsson were the correct inventors ... there is nothing to indicate to [him] that any further "inquiry " into the issue was needed." *Id.* at ¶ 17. As a result of Astra's undisputed failure to fully disclose to Filardi Astra's position that Appelgren and Eskilsson did not invent metoprolol succinate, Filardi did not attempt to interview them or investigate the role of Stenhede and Lilljequist (the chemists at Södertälje) regarding its invention.

The second flawed assumption involves putting the horse before the cart or, at best, circular reasoning. In his declaration, Filardi states that
it made no difference as to priority whether Nitenberg was added or not added [as an inventor to the U.S. application] as a far as claiming priority on the January 1985 U.S. priority application. In either case, the '161 patent would have been entitled to at least the January 1985 U.S. priority date, which is prior to the July 1985 publication date of the Lejus Swedish application.

(Declar. of Filardi ¶ 18) Astra had not given Filardi a copy of the September 19, 1985, memorandum drafted by Wurm highlighting the fundamental issue that the "use of metoprolol succinate became known because Lejus' [published] application was generally available on July [17], 1985, and therefore can be cited as a novelty

reference" to any of Astra's future claims concerning metoprolol succinate. Because Filardi was not provided with the memorandum he was not informed of Wurm's concern that even a victory in the Swedish Patent Office regarding inventorship may be hollow because of the prior art effect of the Lejus publication.

***23** Without this information, Filardi could not have appreciated that Astra's later equivocation of the inventorship issue in January 1989 might need to be disclosed to the USPTO, or at a minimum, might require further investigation as to the true inventor of metoprolol succinate. Because Filardi's legal analysis was directed toward the sole issue of *adding* Nitenberg as an inventor in the '897 patent application, he not aware that there was a genuine dispute that Appengren and Eskilsson were improperly named inventors and that the '897 application may not be entitled to priority to the January 1985 United States application.

If Astra had prevailed with either the Swedish Patent Office or with Lejus in naming Nitenberg as the sole inventor of metoprolol succinate, the claim to metoprolol succinate (in the '161 patent application and in the '154 patent application) would not have been entitled to priority to the January 1985 United States application which listed only Appelgren and Eskilsson as inventors. So Filardi's statement in his declaration that adding Nitenberg made no difference would be correct if either Appelgren and Eskilsson were also still a named inventor. Filardi's statement would be incorrect, however, if Nitenberg replaced both Appelgren and Eskilsson as the inventor. Astra did not give Filardi a chance to consider such a scenario because it failed to provide him with the complete facts concerning its three year dispute with Lejus about inventorship.

Based on the Astra's failure to fully disclose the inventorship dispute to Filardi, I find that Filardi was prevented by Astra from considering information that would have led to a disclosure of the inventorship dispute to the USPTO.

Astra has submitted a declaration of then in-house counsel Nasman in opposition to summary judgment. Defendants assert that this evidence should not be considered based on Astra's failure to identify Nasman as a person with information regarding the inventorship dispute in Astra's Rule 26(a) disclosures and in responses to Defendants' discovery requests.

Even if I were to consider Nasman's declaration, however, it does not change my conclusion that he and Astra failed to be fully candid in providing information to Filardi so that Filardi could make informed decisions regarding the duty of candor and disclosure to the USPTO. Nasman's declaration states in a conclusory fashion that during the telephone call of January 11, 1989, Filardi provided him with advice on the issue of inventorship and that based on Filardi's advice Nitenberg "was not an inventor and that Mr. Appelgren and Ms. Eskilsson were the proper inventors." (Declar. of Nasman at ¶ 17) Because Nasman and Astra failed to provide Filardi with all the information that Astra had regarding its concern with Lejus' July 17, 1985 publication and Astra's three-year inventorship dispute with Lejus (seeking not just to *add* Nitenberg to the patent applications but asserting that Nitenberg be named as *the* inventor of metoprolol succinate) Filardi's advice cannot be relied upon by Nasman to justify his conclusion concerning inventorship.

***24** Nasman's declaration further states that he concluded from his own investigation that Nitenberg should not be a named inventor. However, in his deposition taken after this declaration was made, Nasman states that his investigation consisted of (1) reviewing the Nitenberg lab protocol document, (2) reviewing the Lejus Swedish Application to which Astra claimed priority, and (3) talking to Filardi by telephone in January 1989. (Defs. Reply Memo. Ex. 11 at 66, 73, and 77) I need not consider the contradictions between Nasman's declaration and his deposition testimony. Whether Nasman conducted a minimally competent investigation as to who invented metoprolol succinate does not matter at this stage of the lawsuit. In the present summary judgment context, the question of whether the correct inventors were named in the patents in suit is secondary because the undisputed question of

inequitable conduct centers around the failure of Astra to inform the USPTO about its long-running inventorship dispute with Lejus. It is undisputed in the record that Nasman and Astra failed to fully disclose material information to its United States patent counsel, Filardi, concerning Astra's inventorship dispute with Lejus.

A finding of inequitable conduct

Contradictory evidence abounds concerning whether Appelgren and Eskilsson were the true inventors of metoprolol succinate. Although the contradictions are predominately created by Astra's post-deposition declarations and are subject to be discounted, enough material facts are in dispute to prevent summary judgment on the issue of whether Astra submitted false information regarding inventorship to the USPTO.

Clear and convincing evidence, however, has established that Astra and Lejus were engaged in an prolonged dispute over inventorship of metoprolol succinate and this dispute was not disclosed to the USPTO. The undisputed documents establish that the dispute regarding inventorship spanned more than a three-year period. Inventorship is very material information in a patent prosecution. There was a substantial likelihood that a reasonable examiner would have considered the inventorship dispute between Astra and Lejus important in deciding whether to allow the '161 and '514 patent applications to issue.

Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the USPTO, which includes a duty to disclose to the USPTO all information known to that individual to be material to patentability as defined in this section. 37 C.F.R. § 1.56. "Close cases should be resolved by disclosure, not unilaterally by the applicant." *LaBounty Mfg., Inc. v. United States International Trade Commission,* 958 F.2d 1066, 1076 (Fed.Cir.1992). Disputes concerning inventorship are material information that need to be disclosed. *PerSeptive Biosystems, Inc.,* 225 F.3d at 1321.

On March 25, 1988, Lejus filed, on Astra's behalf, the '897 (which became the '161 patent and the '154 patent) naming Appelgren and Eskilsson as inventors. At that time Astra had been asserting to Lejus for more than two years that Nitenberg had solely invented metoprolol succinate through letters and by initiating an inventorship dispute with the Swedish Patent Office. *Even after the patent application was filed* Astra's counsel wrote to Lejus to demand that Nitenberg be listed as *the* inventor of metoprolol succinate in the European and United States patent applications filed per their agreement.

***25** Yet Lejus failed to disclose this long-running material dispute to the USPTO in its filing and prosecution of the '897 application. Nor did Astra disclose this information to the USPTO. Although Astra's United States patent counsel, Filardi, believed he made all of the disclosures necessary, Astra failed to provide him with important and material information concerning its dispute with Lejus. Astra cannot benefit from its failure to disclose material information to its United States patent counsel and then hide behind its argument that he acted in good faith and candor in his prosecution of the patent. It was Astra's own failure to disclose which led Filardi to believe he was disclosing all information known to be material to patentability. Astra's employee Nasman was an individual associated with the filing and prosecution of the patent application and had a duty of candor and good faith to the USPTO. Nasman was fully aware of the extent of the inventorship dispute. Nonetheless, Nasman and Astra failed to fully disclose the inventorship dispute with Lejus to Filardi which prevented the possibility of the dispute from being disclosed to the USPTO.

I do not believe that the question of whether to disclose the inventorship dispute was a close call. To find otherwise is to find that Astra's filing with the Swedish Patent Office and its three-year dispute with Lejus were pursued in bad faith.

Not only was the issue of the dispute of inventorship highly material, Astra had a strong incentive to not disclose the dispute. If a patent examiner had learned of the dispute and found Nitenberg to be the sole inventor of metoprolol

succinate, the '897 patent application would not have been entitled to priority to the January 1985 United States application. The effective filing date for the '897 patent would have been March 25, 1988. As a consequence, Astra's metoprolol succinate patents may have been denied as anticipated by the prior art of the publication of the Lejus' European application on July 17, 1985.

I find by clear and convincing evidence that the inventorship dispute between Astra and Lejus was highly material and should have been disclosed to the USPTO during the prosecution of the patents in suit. I also find by clear and convincing evidence that Astra's motivation to not reveal the dispute was great based on the risk of losing its metoprolol succinate inventions as anticipated by prior art. The intent to deceive is clearly present. Afer weighing materiality and intent I find that Astra's conduct was so culpable that its '161 patent and '154 patent are unenforceable.

Conclussion

I find by clear and convincing evidence that Astra's '161 patent and "154 patent are invalid on the basis of double patenting over the '318 patent. I also find by clear and convincing evidence that the '161 patent is not entitled to priority to the '318 patent application filing date. As a consequence I find that the '161 patent is invalid as anticipated.

***26** Finally, I find by clear and convincing evidence that the '161 patent and '154 patent are unenforceable based on Astra's inequitable conduct in the prosecution of these patents in the United States Patent and Trademark Office. Astra failed to disclose to the USPTO the material dispute it had with Lejus concerning inventorship of metoprolol succinate. The failure to disclose was done with an intent to deceive the patent examiner as to this material dispute. Astra failed to provide material information in order to avoid questions concerning Astra's ability to claim priority to the '318 patent application and to avoid potential prior art concerning metoprolol succinate.

Accordingly,

IT IS HEREBY ORDERED that Defendants' Motion for Summary Judgment of Invalidity [# 120] is GRANTED. Plaintiffs' Motion for Partial Summary Judgment of No Invalidity of United States Patent 5,081,164 for Double Patenting [# 297] is DENIED.

IT IS FURTHER ORDERED that Defendants' Motion for Summary Judgment Seeking a Declaration that United States Patent Nos. 5,001,161 and 5,081,154 are Unenforccable for Inequitable Conduct [# 241] is GRANTED.

IT IS FURTHER ORDERED that all other pending motions in this case are DENIED as moot.

E.D.Mo.,2006.
In re Metoprolol Succinate Patent Litigation
Slip Copy, 2006 WL 120343 (E.D.Mo.)

Briefs and Other Related Documents (Back to top)

- 2005 WL 3726145 (Trial Motion, Memorandum and Affidavit) Defendants' Memorandum in Opposition to Astra's Motion (D.I. 297) for Partial Summary Judgment That U.S. Patent No. 5,081,154 is Not Invalid for Double Patenting (Oct. 6, 2005) Original Image of this Document (PDF)
- 2005 WL 3726144 (Trial Motion, Memorandum and Affidavit) Plantiffs' Memorandum in Opposition to defendants' Motion for Summary Judgment Ý#1201¨ (Feb. 14, 2005) Original Image of this Document (PDF)
- 2005 WL 3726341 () Expert Declaration of Gerald S. Brenner. Ph.D. (Feb. 11, 2005) Original Image of this Document (PDF)
- 2005 WL 3726143 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Memorandum in Support of Their Motion to Compel Supplemental Responses to Interrogatories (Feb. 1, 2005) Original Image of this Document (PDF)
- 2005 WL 3726142 (Trial Motion, Memorandum and Affidavit) Plaintiffs Astrazeneca's Memorandum in Opposition to Andrx's Motion to Compel Plaintiffs to Answer 30(b)(6) Deposition Questions and Sanctions Against Plaintiffs (Jan. 6, 2005) Original Image of this Document (PDF)
- 2004 WL 3682640 (Trial Motion, Memorandum and Affidavit) Defendants' Memorandum of Law in

Support of Motion for Summary Judgment of Invalidity (Dec. 30, 2004) Original Image of this Document (PDF)
• 2004 WL 3682650 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Memorandum in Opposition to Defendants' Motion to Compel Production of Patent Prosecution Documents (Dec. 13, 2004) Original Image of this Document (PDF)
• 2004 WL 3682663 (Trial Pleading) Eon's Second Amended Answer to Amended Complaint (Dec. 7, 2004) Original Image of this Document (PDF)
• 2004 WL 3682649 (Trial Motion, Memorandum and Affidavit) Defendants' Memorandum in Support of its Motion to Compel Production of Patent Prosecution Documents (Dec. 2, 2004) Original Image of this Document (PDF)
• 2004 WL 3682662 (Trial Pleading) First Amended Answer and Counterclaim (Dec. 2004) Original Image of this Document (PDF)
• 2004 WL 3682647 (Trial Motion, Memorandum and Affidavit) Defendants', Andrx Corporation and Andrx Pharmaceuticals, LLC, Memorandum in Support of Their Motion to compel the Designation and Production of 30(b)(6) Witnesses (Nov. 15, 2004) Original Image of this Document (PDF)
• 2004 WL 3682644 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Memorandum in Opposition to Defendants' Motion to Compel Production of Patent Prosecution Documents (Oct. 7, 2004) Original Image of this Document (PDF)
• 2004 WL 3682645 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Opposition to Defendant's Motion to Compel Answers to Interrogatories (Oct. 7, 2004) Original Image of this Document (PDF)
• 2004 WL 3682646 (Trial Motion, Memorandum and Affidavit) Defendants', Andrx Pharmaceuticals, LLC and Andrx Corporation, Memorandum in Support of Motion to Compel Plaintiffs to Answer Interrogatories, Respond to Requests for Admissions and Produce Documents (Oct. 7, 2004) Original Image of this Document (PDF)
• 2004 WL 3682642 (Trial Motion, Memorandum and Affidavit) Defendants' Memorandum in Support of Its Motion to Compel Production of Patent Prosecution Documents (Oct. 1, 2004) Original Image of this Document (PDF)
• 2004 WL 3682643 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Memorandum in Support of Its Motion to Compel Andrx to Produce Documents and Answer Interrogatories (Oct. 1, 2004) Original Image of this Document (PDF)
• 2004 WL 3682641 (Trial Motion, Memorandum and Affidavit) Memorandum in Support of Defendants' Motion for Judgment on the Pleadings of no Willful Infringement (Sep. 28, 2004) Original Image of this Document (PDF)
• 4:04md01620 (Docket) (Aug. 11, 2004)
• 2004 WL 3690593 () Expert Declaration of Gerald S. Brenner, Ph.D. (2004) Original Image of this Document (PDF)

END OF DOCUMENT

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-969

JUL 31 2006

Sandoz Inc.
Attention: Dietrich Bartel, B.S.
Director, Regulatory Affairs
4700 Sandoz Drive
Wilson, NC 27893

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 18, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Metoprolol Succinate Extended-Release Tablets USP, 25 mg, 50 mg, 100 mg and 200 mg.

Reference is also made to your amendments dated May 13, 2005; March 28, June 1, and June 19, 2006. We acknowledge receipt of your correspondences dated February 11, and April 2, 2004; April 20, and July 21, 2005; and January 23, 2006, addressing the patent and exclusivity issues associated with this ANDA.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, because of the 180-day generic drug exclusivity issue explained below, at this time we are unable to grant final approval to your Metoprolol Succinate Extended-Release Tablets USP, 50 mg, 100 mg and 200 mg. Therefore, only your Metoprolol Succinate Extended-Release Tablets USP, 25 mg is approved. Your Metoprolol Succinate Extended-Release Tablets USP, 50 mg, 100 mg and 200 mg strengths are tentatively approved and will not be eligible for final approval until the 180-day generic drug exclusivity period associated with these strengths has expired.

The referenced listed drug (RLD) upon which you have based your ANDA, Toprol-XL® Extended-Release Tablets of AstraZeneca LP (AstraZeneca), is subject to periods of patent protection. The following patents and expiration dates are currently listed in

the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
4,927,640 (the '640 patent)	May 22, 2007
4,957,745 (the '745 patent)	September 18, 2007
5,001,161 (the '161 patent)	September 18, 2007
5,081,154 (the '154 patent)	September 18, 2007

Your ANDA contains paragraph IV certifications to each of the patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Metoprolol Succinate Extended-Release Tablets USP, under this ANDA. You have notified the agency that Sandoz complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '161 and '154 patents was initiated against Sandoz in the United States District Court for the District of Delaware, then transferred and consolidated in the Eastern District of Missouri [Astrazeneca AB, Aktiebolaget Hassle & AstraZeneca LP, v Eon Labs Inc., Civil Action No. 04-CV-0205]. You have also notified the agency that the court decided that '161 and '154 patents are invalid and unenforceable. Therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

I. Approval of Metoprolol Succinate Extended-Release Tablets USP, 25 mg

The Division of Bioequivalence has determined your Metoprolol Succinate Extended-Release Tablets USP, 25 mg, to be bioequivalent and, therefore, therapeutically equivalent to the referenced listed drug, Toprol-XL of AstraZeneca.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. The "interim" dissolution specifications are as follows:

Apparatus:	(b)(4) [redacted]
Speed:	
Medium:	
Volume:	

Specifications:

1 hr:	(b)(4) [redacted]
4 hrs:	
8 hrs:	
20 hrs:	

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement - Changes Being Effected when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

With respect to 180-day generic drug exclusivity for Metoprolol Succinate Extended-Release Tablets USP, 25 mg, Sandoz was the first ANDA applicant to submit a substantially complete ANDA for Metoprolol Succinate Extended-Release Tablets USP, 25 mg, with a paragraph IV certification to the four patents listed above. Therefore, with this approval, Sandoz may be eligible for 180 days of generic drug exclusivity for Metoprolol Succinate Extended-Release Tablets USP, 25 mg. Generic drug exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, begins to run from the date of commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins. The agency notes that Sandoz failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the Act. However, the agency is not making a formal determination at this time of Sandoz's eligibility for 180-day generic drug exclusivity. It will do so only if another applicant becomes eligible for approval within 180 days after Sandoz begins commercial marketing of Metoprolol Succinate Extended-Release Tablets USP, 25 mg.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of Metoprolol Succinate Extended-Release Tablets USP, 25 mg.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

II. Tentative Approval of Metoprolol Succinate Extended-Release Tablets USP, 50 mg, 100 mg and 200 mg.

We are unable to grant final approval to your Metoprolol Succinate Extended-Release Tablets USP, 50 mg, 100 mg and 200 mg, at this time because other ANDAs providing for the 50 mg, 100 mg, and 200 mg strengths and containing paragraph IV certifications to the patents listed in the Orange Book were submitted to the agency prior to the submission of your ANDA. Other ANDAs, therefore, are entitled to 180-day generic drug exclusivity for Metoprolol Succinate Extended-Release Tablets USP, 50 mg, 100 mg, and 200 mg. Accordingly, your Metoprolol Succinate Extended-Release Tablets USP, 50 mg, 100 mg and 200 mg will be eligible for final approval on the date that is 180 days after the agency receives notice, with respect to the other ANDAs, of the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv) of the Act.[1]

---

[1] Because the other ANDAs, unlike yours, were filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

Our tentative approval of your Metoprolol Succinate Extended-Release Tablets USP, 50 mg, 100 mg and 200 mg, is based upon information currently available to the agency, i.e., data in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product. This decision is subject to change on the basis of new information that may come to our attention.

To reactivate this ANDA to provide for final approval of the 50 mg, 100 mg and 200 mg strengths, please submit a "Supplemental Application - Expedited Review Requested" 90 days prior to the date you believe that these products will be eligible for final approval. Your supplement must provide a summary of the legal basis upon which you believe the ANDA should be approved, as well as:

1. updated information related to final-printed labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this ANDA, or
2. a statement that no such changes have been made to the ANDA since the date of tentative approval.

Any changes in the conditions outlined in this ANDA and the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to agency review before final approval of the 50 mg, 100 mg and 200 mg strengths will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt.

In addition to the supplement requested above, the agency may request at any time prior to the final date of approval that you submit an additional supplement containing the requested information. Failure to submit either supplement may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

Your Metoprolol Succinate Extended-Release Tablets USP, 50 mg, 100 mg and 200 mg, may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of a drug before the effective final approval date is prohibited under section 501 of the Act. Also, until the agency issues the final

approval letter, the 50 mg, 100 mg, 200 mg strengths will not be listed in the "Orange Book."

For further information on the status of this ANDA, or prior to submitting a supplement providing for the final approval of your Metoprolol Succinate Extended-Release Tablets USP, 50 mg, 100 mg and 200 mg, please contact Cheryl Wiseman, Project Manager, at 301-827-5806.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research


EXHIBIT C

LEXSEE 2006 US DIST LEXIS 36015

U.S. HORTICULTURAL SUPPLY, INC., Plaintiff, v. THE SCOTTS COMPANY, et al., Defendants

CIVIL ACTION NO. 04-5182

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

2006 U.S. Dist. LEXIS 36015; 2006-1 Trade Cas. (CCH) P75,303

June 1, 2006, Decided
June 1, 2006, Filed; June 2, 2006, Entered

PRIOR HISTORY: *U.S. Horticultural Supply, Inc. v. Scotts Co., 2005 U.S. Dist. LEXIS 14573 (E.D. Pa., July 20, 2005)*

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff competitor alleged that defendant horticultural company conspired with a supplier to restrain trade in the mid-Atlantic and/or New England market for horticultural products and the company's brand-name horticultural products in violation of § 1 of the Sherman Act. The company moved to dismiss.

OVERVIEW: The result of the alleged conspiracy was that the competitor went out of business and the supplier was able to purchase the competitor's assets at distressed levels. As a result of the competitor's demise, inter-brand competition with the company's products was reduced and the supplier allegedly raised the prices of the company brand products to supra-competitive levels. The complaint alleged that all of the actions taken by the company were done to carry out a joint plan with the supplier to drive the competitor out of the market, reduce competition with competing brands, and raise prices. Although at some point the competitor would need to put forth evidence, beyond bare allegations, that tended to exclude unilateral conduct, at this stage, the court could not rule out the possibility that the company may not have decided to stop doing business with the competitor unilaterally unless it had some assurances that another distributor would be in a position to take over for the competitor, charge higher prices, and reduce competition from other brands. Thus, dismissal of the competitor's § 1 of the Sherman Act, *15 U.S.C.S. § 1*, claim was not appropriate.

OUTCOME: The court denied the company's motion to dismiss.

LexisNexis(R) Headnotes

Civil Procedure > Pleading & Practice > Defenses, Demurrers, & Objections > Failures to State Claims

[HN1] When considering a motion to dismiss under *Fed. R. Civ. P. 12(b)(6)*, a court accepts all facts and allegations listed in the complaint as true and construes them in the light most favorable to the plaintiff. A complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.

Antitrust & Trade Law > Sherman Act > Coverage > General Overview

[HN2] Section 1 of the Sherman Act, *15 U.S.C.S. § 1*, provides that every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several states, or with foreign nations, is hereby declared to be illegal. Courts have long recognized that § 1 only prohibits unreasonable restraints of trade.

Antitrust & Trade Law > Sherman Act > Claims

[HN3] Generally, to establish a violation of § 1 of the Sherman Act, *15 U.S.C.S. § 1*, a plaintiff must prove: (1) concerted activity by the defendants; (2) that produced anti-competitive effects within the relevant product and geographic markets; (3) that the concerted action was illegal; and (4) that the plaintiff was injured as a proximate result of the concerted action. When a conspiracy to

commit a per se violation of § 1 is alleged though, a plaintiff need only prove a conspiracy existed that was the proximate cause of the plaintiff's injuries.

Antitrust & Trade Law > Sherman Act > Claims
Civil Procedure > Pleading & Practice > Pleadings > Complaints > Requirements
[HN4] Generally, claims under § 1 of the Sherman Act, *15 U.S.C.S. § 1*, are held to the pleading standard laid out in *Fed. R. Civ. P. 8(a)* which requires a short and plain statement of the claim. Courts should be extremely liberal in construing antitrust complaints. However, a general allegation of conspiracy, without more is not sufficient. Although detail is not necessary, a plaintiff must plead the facts constituting the conspiracy, its object and accomplishment.

Antitrust & Trade Law > Sherman Act > Claims
[HN5] In the context of a summary judgment motion, a plaintiff seeking damages for a violation of § 1 of the Sherman Act, *15 U.S.C.S. § 1*, must present evidence that tends to exclude the possibility that the alleged conspirators acted independently.

Antitrust & Trade Law > Price Fixing & Restraints of Trade > Per Se Rule & Rule of Reason > Sherman Act
Antitrust & Trade Law > Sherman Act > Claims
[HN6] If the plaintiff has alleged a conspiracy to commit a per se violation of § 1 of the Sherman Act, *15 U.S.C.S. § 1*, the plaintiff only has to plead facts which, if true, could show that defendant was the proximate cause of the plaintiff's injuries. Otherwise the plaintiff must proceed under the rule of reason and also plead facts which, if true, could demonstrate an anti-competitive effect within the relevant product and geographical markets.

Antitrust & Trade Law > Price Fixing & Restraints of Trade > Vertical Restraints > Price Fixing
[HN7] For a vertical agreement between a manufacturer and a dealer to terminate a second dealer to be illegal per se, the non-terminated dealer must expressly or impliedly agree to set its prices at some level, though not a specific one.

COUNSEL: [*1] For U.S. HORTICULTURAL SUPPLY, INC., formerly known as E.C. GEIGER, INC., Plaintiff: JOSEPH J. HAMILL, PETER A. VONMEHREN, TIMOTHY C. RUSSELL, SPECTOR GADON & ROSEN PC, PHILADELPHIA, PA.

For THE SCOTTS COMPANY, Defendant: PETER B. GRONVALL, HUNTON & WILLIAMS LLP, WASHINGTON, DC; THOMAS G. SLATER, JR., HUNTON & WILLIAMS, RICHMOND, VA; AMY S. KLINE, SAUL EWING LLP, PHILADELPHIA, PA.

JUDGES: MARY A. McLAUGHLIN, J.

OPINIONBY: MARY A. McLAUGHLIN

OPINION:

MEMORANDUM AND ORDER

McLaughlin, J.

June 1, 2006

The plaintiff has alleged that the Scotts Company ("Scotts") conspired with Griffin Greenhouse Supplies, Inc. ("Griffin") to restrain trade in the mid-Atlantic and/or New England market for horticultural products and Scotts brand horticultural products in violation of *Section 1 of the Sherman Act*. Scotts has moved to dismiss the plaintiff's complaint pursuant to *Federal Rule of Civil Procedure 12(b)(6)* for failure to state a claim. The Court will deny Scotts' motion.

I. Procedural History

The plaintiff originally sued Scotts on February 7, 2003 and brought an attempted monopolization claim against Scotts pursuant to *Section 2 of the Sherman Act*. The [*2] plaintiff also made allegations of promissory estoppel and breach of contract. Scotts moved to dismiss the Sherman Act claim and the promissory estoppel claims. The plaintiff then withdrew the promissory estoppel claims and after some discovery, agreed to withdraw the *Section 2* claim as well. On July 20, 2005, the Court granted Scotts' motion for summary judgment with respect to the breach of contract claim.

On September 29, 2004, while the plaintiff was still litigating the *Section 2* claim, the Court denied the plaintiff's motion for leave to amend to add a claim under *Section 1 of the Sherman Act*. Following that decision, the plaintiff filed this complaint on November 5, 2004 against Scotts and Griffin. Scotts filed a motion to dismiss on December 2, 2004 and oral arguments were held on March 18, 2005. At the oral arguments, a representation was made that the plaintiff settled with Griffin, so only Scotts remains as a defendant.

II. Factual Background n1

n1[HN1] When considering a motion to dismiss under *Fed. R. Civ. P. 12(b)(6)*, a court accepts all facts and allegations listed in the complaint as true and construes them in the light most favorable to the plaintiff. *H.J., Inc. v. Nw. Bell Tel. Co., 492 U.S. 229, 249, 109 S. Ct. 2893, 106 L. Ed. 2d 195 (1989)*; *Rocks v. City of Philadelphia, 868 F.2d 644, 645 (3d Cir. 1989)*. "[A] complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson, 355 U.S. 41, 45-46, 78 S. Ct. 99, 2 L. Ed. 2d 80 (1957)*.

[*3]

In support of its *Section 1* claim, the plaintiff, a former distributor of horticultural products in the mid-Atlantic region, alleges that Scotts, a supplier of horticultural products, conspired with another one of its distributors, Griffin, to restrain trade in the mid-Atlantic and New England market for horticultural products and Scotts brand horticultural products. The plaintiff alleges that the objects of the conspiracy were: (i) to eliminate the plaintiff as a competitor to Griffin by preventing the plaintiff from entering the New England market and driving the plaintiff out of the mid-Atlantic market; (ii) to prevent the plaintiff from selling horticultural products from other manufacturers that competed with Scotts; (iii) to prevent the plaintiff from selling Scotts' products at lower prices than Scotts desired; and (iv) to raise the prices of Scotts branded products.

To accomplish the objects of the conspiracy, the plaintiff claims that Scotts and Griffin agreed that: (i) Scotts would assist Griffin in entering the mid-Atlantic market; (ii) Scotts would hinder the plaintiff from entering the New England market to compete with Griffin; (iii) Scotts would impose unreasonable [*4] credit terms and other costs on the plaintiff so that the plaintiff could not survive as a competitor to Griffin; and (iv) after the plaintiff had been eliminated as a competitor, Griffin would increase the prices it charged for Scotts branded products to supra-competitive levels.

The result of this alleged conspiracy was that the plaintiff did go out of business and Griffin was able to purchase the plaintiff's assets at distressed levels. As a result of the plaintiff's demise, inter-brand competition with Scotts' products was reduced and Griffin raised the prices of Scotts brand products to supra-competitive levels.

III. Legal Analysis

[HN2] *Section 1 of the Sherman Act* provides: "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is hereby declared to be illegal." *15 U.S.C. § 1*. Courts have long recognized that *Section 1* only prohibits unreasonable restraints of trade. *Business Electronics Corp. v. Sharp Electronics Corp., 485 U.S. 717, 723, 108 S. Ct. 1515, 99 L. Ed. 2d 808 (1988)*.

[HN3] Generally, to establish a *Section 1* violation, a plaintiff must prove: "(1) [*5] concerted activity by the defendants; (2) that produced anti-competitive effects within the relevant product and geographic markets; (3) that the concerted action was illegal; and (4) that the plaintiff was injured as a proximate result of the concerted action." *Queen City Pizza, Inc. v. Domino's Pizza, Inc., 124 F.3d 430, 442 (3d Cir. 1997)*; *Tunis Bros. Co., Inc. v. Ford Motor Co., 952 F.2d 715, 722 (3d Cir. 1991)*. When a conspiracy to commit a per se violation of *Section 1* is alleged though, a plaintiff need only prove a conspiracy existed that was the proximate cause of the plaintiff's injuries. *In re Flat Glass Antitrust Litig., 385 F.3d 350, 356 (3d Cir. 2004)*.

Scotts has argued that the complaint should be dismissed because it does not plead facts that are sufficiently specific to support a conspiracy and that the facts it does allege are consistent with unilateral action. Additionally, Scotts argues that even if the complaint properly alleges a conspiracy, it does not allege a per se violation and the plaintiff has not properly alleged an anti-competitive effect or a relevant product or geographic market. Although the Court [*6] has reservations about whether the plaintiff will be able to prove its claims, at this stage in the proceedings, the Court concludes that the plaintiff had pled facts which, if true, could establish a vertical agreement to fix prices that is illegal per se under *Section 1*.

A. Concerted Action

[HN4] Generally, *Section 1* claims are held to the pleading standard laid out in *Federal Rule of Civil Procedure 8(a)* which requires a short and plain statement of the claim. *Lum v. Bank of Am., 361 F.3d 217, 228 (3d Cir. 2004)*. Courts "'should be extremely liberal in construing antitrust complaints.'" Id. (quoting *Knuth v. Erie-Crawford Dairy Coop. Ass'n., 395 F.2d 420, 423 (3d Cir. 1968))*. However, a general allegation of conspiracy, without more is not sufficient. Although detail is not necessary, a plaintiff "must plead the facts constituting the conspiracy, its object and accomplishment." *Black & Yates, Inc. v. Mahogany Ass'n, Inc., 129 F.2d 227, 231 (3d Cir. 1941)*.

Albeit in a slightly different context than this instant case, the United States Court of Appeals for the Third

Circuit dealt with the [*7] question of whether allegations of concerted action in a *Section 1* case were sufficient to survive a motion to dismiss in *Fuentes v. South Hills Cardiology, 946 F.2d 196 (3d Cir. 1991)*. The plaintiff in Fuentes alleged that doctors, who were in competition with the plaintiff, conspired with a hospital to terminate the plaintiff's staff privileges. In sum, the relevant allegations in the complaint stated that: (i) competing doctors requested that the hospital deny the plaintiff staff privileges; (ii) in direct response to this request, the hospital did deny the plaintiff staff privileges; (iii) the denial of staff privileges would not have occurred but for the request by competing doctors; (iv) the defendants' conduct constituted an illegal group boycott under *Section 1*; and (v) the denial of staff privileges at the hospital deprived the plaintiff of the ability to provide health care services in competition with the defendants. *Fuentes, 946 F.2d at 201.*

After referencing the standard from Black & Yates, the Court of Appeals held that the plaintiff's "allegations identifying the conspiracy's participants, purpose and motive are sufficient to [*8] survive a motion to dismiss." *Id. at 202*. This was so even though the plaintiff had not identified any meetings or phone calls at which the conspiracy was carried out. Id.

In this case, although the complaint lacks detail about how the alleged conspiracy was formed, it is sufficiently specific to survive a motion to dismiss.

First, the complaint identifies Scotts and Griffin as the participants in the conspiracy and alleges that its purpose was to drive the plaintiff out of the mid-Atlantic market, replace it with Griffin, raise the prices of Scotts branded products and reduce inter-brand competition with Scotts branded products. The ultimate motive of Scotts and Griffin is easily inferred as a desire to increase profits. (Compl. PP1, 18).

Additionally, the complaint goes into some detail as to how Scotts and Griffin accomplished and carried out their agreement. The complaint alleges that the conspiracy was formed in about 1998. Initially, Griffin obtained Scotts' permission to distribute Scotts branded products in the mid-Atlantic market and in about 1998 Griffin entered that market. Scotts facilitated Griffin's entry by shipping products directly to certain [*9] high-volume, high-profit buyers thereby saving Griffin storage and distribution costs. At the same time that Scotts was assisting Griffin's entry into the mid-Atlantic market, it is alleged that Scotts denied the plaintiff the ability to compete with Griffin in the New England market and imposed onerous credit restrictions on the plaintiff. In 2002, Scotts ceased doing business with the plaintiff, after repeated promises that the plaintiff's distribution agreement would be renewed and following discussions between the plaintiff and Scotts regarding the plaintiff's distribution of certain non-Scotts brand products. This left the plaintiff without adequate supply arrangements for horticultural products and drove the plaintiff out of business. Griffin was then able to purchase the plaintiff's assets at a low price. Following this, Griffin raised the prices it charged for Scotts brand products to supra-competitive levels. (Compl. PP1-2, 17-42).

Scotts relies on *Zimmerman v. PepsiCo., Inc., 836 F.2d 173 (3d Cir. 1988)*, a case decided prior to Fuentes, to support its argument that the plaintiff's allegations of a *Section 1* conspiracy are not sufficiently particularized [*10] to withstand a motion to dismiss. At issue in PepsiCo was whether the plaintiff had alleged facts sufficient to support a claim that the defendants committed a per se *Section 1* violation by forming a horizontal conspiracy. Although the Soft Drink Act governed the plaintiff's allegations, the United States Court of Appeals for the Third Circuit considered in detail the question of whether the plaintiff had pleaded a per se violation of the Sherman Act based on a horizontal conspiracy that would exempt the case from the requirements of the Soft Drink Act. However, the Court of Appeals concluded that because of the Soft Drink Act, the plaintiff had a much higher pleading burden than that in a typical antitrust case. *PepsiCo, 836 F.2d at 181.*

The complaint alleged that PepsiCo, two licensed bottlers and other unnamed co-conspirators agreed to reduce competition between bottlers and resellers by prohibiting sales between resellers. Specifically, the complaint alleged that the defendants and their co-conspirators would refuse to sell to and would otherwise penalize resellers who bought PepsiCo products from or sold PepsiCo products to other resellers. The defendants [*11] and their co-conspirators would track such sales by a coding identification system. *Id. at 180.*

The Court of Appeals concluded that the complaint did not state a horizontal conspiracy claim which would exempt it from the Soft Drink Act. In reaching that conclusion, the Court of Appeals found that: (1) the complaint did not properly identify the co-conspirators and did not allege any agreement that was attributable solely to bottlers, without the involvement of PepsiCo; and (2) there were no allegations of any communications between the defendant bottlers or other means by which any alleged agreement came about. *Id. at 181.*

Even disregarding the fact that a higher pleading burden was imposed on the plaintiff in *PepsiCo* as a result of the Soft Drink Act, the plaintiff's complaint in this case is distinguishable from the complaint in that case.

First, in this case, the plaintiff's complaint identifies the participants by name and makes an allegation of an agreement which, if true, would constitute the vertical

agreement which forms the basis of the plaintiff's *Section 1* claim. The complaint in PepsiCo, which alleged a horizontal agreement, [*12] failed to allege an agreement solely among competing bottlers.

Second, although the plaintiff's complaint makes only bare-bones allegations of specific communications between Scotts and Griffin, n2 the lack of such allegations alone does not require dismissal. See *Fuentes, 946 F.2d at 202*. Additionally, the plaintiff's complaint does go into detail about the means employed to carry out the alleged agreement. Thus, dismissal is not required under PepsiCo.

> n2 Besides the general allegation that Scotts and Griffin conspired, the only allegation of a specific communication between Scotts and Griffin is an allegation in paragraph 18 of the complaint which states that Griffin sought and obtained Scotts' permission to enter the mid-Atlantic market.

Lack of specificity aside, Scotts has also argued that the plaintiff's *Section 1* claim must be dismissed because the complaint does not allege facts which are inconsistent with unilateral action. In *Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986),* [*13] the Supreme Court held that [HN5] in the context of a summary judgment motion, "a plaintiff seeking damages for a violation of *§ 1* must present evidence 'that tends to exclude the possibility' that the alleged conspirators acted independently." *Matsushita, 475 U.S. at 588* (quoting *Monsanto Co. v. Spray-Rite Serv. Corp., 465 U.S. 752, 764, 104 S. Ct. 1464, 79 L. Ed. 2d 775 (1984))*. Although Matsushita did not deal with a motion to dismiss, its reasoning has been applied in this context. See *Brunson Commc'ns Inc. v. Arbitron, Inc., 239 F. Supp. 2d 550, 563-564 n.5 (E.D. Pa. 2002)* (citing cases). The Court of Appeals in PepsiCo also found Matsushita relevant in the context of a motion to dismiss, but did not directly apply its reasoning. *PepsiCo, 836 F.2d at 181-82*.

Cases that have applied Matsushita in the context of a motion to dismiss have not required a plaintiff to put forth evidence that tends to exclude the possibility that the defendants acted independently, but instead look to the facts alleged in the complaint to see if they support an inference of an agreement. For example, in Brunson, the district court applied [*14] Matsushita and dismissed the complaint because the allegations were "not sufficient to support an inference that defendants acted conspiratorially." *Brunson, 239 F. Supp. 2d at 563-64*. Similarly, the cases cited by Brunson to support the application of Matsushita found that dismissal was warranted when the alleged conspiracy was illogical, made no economic sense, or when the facts, viewed in the light most favorable to the plaintiff, did not support an antitrust claim. See *DM Research, Inc. v. College of Am. Pathologists, 2 F. Supp. 2d 226, 229-230 (D.R.I. 1998)* (aff'd *170 F.3d 53*); *United Magazine Co. v. Murdoch Magazines Distrib. Inc., 146 F. Supp. 2d 385, 401-02 (S.D.N.Y. 2001)*; *Cancall PCS, LLC v. Omnipoint Corp., No. 99-3395, 2000 U.S. Dist. LEXIS 2830 at *23 n.4 (S.D.N.Y Mar. 6, 2000)*. These decisions are consistent with Fuentes which held that a complaint should not be dismissed even though there was a competing inference of unilateral action. *Fuentes, 946 F.2d at 202*.

The Court does not have to decide whether Matsushita is applicable here, because even applying [*15] Matsushita to the plaintiff's complaint, the Court concludes that the complaint states a plausible claim for a conspiracy.

The parties do not dispute that Scotts would have been justified under the antitrust laws if Scotts had unilaterally decided to choose Griffin over the plaintiff as a distributor for its products in the mid-Atlantic region and the most likely inference to be drawn from the plaintiff's allegations is that Scotts did just that. Any subsequent price increase or refusal to sell competing products by Griffin is likely due to an independent decision by Griffin.

That said, the complaint alleges that all of the actions taken by Scotts were done to carry out a joint plan with Griffin to drive the plaintiff out of the market, reduce competition with competing brands and raise prices. Although at some point the plaintiff will need to put forth evidence, beyond bare allegations, that tends to exclude unilateral conduct, at this stage, the Court cannot rule out the possibility that Scotts may not have decided to stop doing business with the plaintiff unilaterally unless it had some assurances that another distributor would be in a position to take over for the plaintiff, [*16] charge higher prices and reduce competition from other brands. Thus, dismissal is not appropriate at this stage even applying *Matsushita*. See *Fuentes 946 F.2d at 202*.

B. Per Se Violation

The next issue is whether the alleged conspiracy constitutes a per se violation of the Sherman Act. [HN6] If the plaintiff has alleged a conspiracy to commit a per se violation of *Section 1*, the plaintiff only has to plead facts which, if true, could show that Scotts was the proximate cause of the plaintiff's injuries. *In re Flat Glass Antitrust Litig., 385 F.3d 350, 356 (3d Cir. 2004)*. Otherwise the plaintiff must proceed under the rule of reason and also plead facts which, if true, could demonstrate an anti-competitive effect within the relevant prod-

uct and geographical markets. See *Tunis Bros. Co., Inc. v. Ford Motor Co., 952 F.2d 715, 722 (3d Cir. 1991)*.

In *Business Electronics Corp. v. Sharp Electronics Corp., 485 U.S. 717, 108 S. Ct. 1515, 99 L. Ed. 2d 808 (1988)*, the Supreme Court addressed the question of when a vertical agreement results in a per se violation of *Section 1*. Business Electronics involved a situation where Sharp terminated [*17] one of its dealers, Business Electronics, because of price cutting and pursuant to an agreement with another dealer. *Bus. Elecs., 485 U.S. at 722*. The Supreme Court agreed with the United States Court of Appeals for the Fifth Circuit which held that [HN7] for a vertical agreement between a manufacturer and a dealer to terminate a second dealer to be illegal per se, the non-terminated dealer must "expressly or impliedly agree to set its prices at some level, though not a specific one." *Id. at 722, 726* (internal quotations omitted).

In this case, the plaintiff has alleged facts, which if proven, could establish a per se violation of the Sherman Act under *Business Electronics*. The complaint alleges that Scotts and a dealer, Griffin, conspired to eliminate another dealer, the plaintiff, because of the plaintiff's price cutting and sales of non-Scotts branded products. It is alleged that part of the conspiracy was an agreement between Scotts and Griffin that Griffin would raise prices to supra-competitive levels once the plaintiff had been eliminated. Once the plaintiff was no longer in business, it is alleged that Griffin did indeed raise prices for Scotts [*18] branded products and/or other horticultural products to supra-competitive levels. n3 (Compl. PP1-2, 18, 42).

> n3 Scotts has argued that depositions in a related case undermine the plaintiff's allegation of price-fixing. At this stage though, the Court will not look beyond the complaint to discovery taken in a related case.

Scotts has not argued that the plaintiff failed to plead facts which, if true, could demonstrate that the alleged conspiracy was the proximate cause of the plaintiff's injuries. Thus, the plaintiff has stated a claim under *Section 1*. See *In re Flat Glass Antitrust Litigation, 385 F.3d 350, 356 (3d Cir. 2004)*. Because the plaintiff has pled a per se violation of the Sherman Act, at this stage, the Court need not consider Scotts' arguments that the plaintiff has not adequately pled an anti-competitive effect in a relevant product or geographical market.

IV. Conclusion

Since Scotts terminated its distribution agreement with the plaintiff in late 2002, there have been [*19] a number of lawsuits between the plaintiff and Scotts in both this Court and in other fora. Prior to this case, the plaintiff filed a *Section 2* claim against Scotts that the plaintiff agreed to dismiss after insufficient evidence was found during discovery to support its allegations. However, despite the fact that there has been extensive litigation of related claims, this instant claim was filed as a new case and the defendants filed a motion to dismiss for failure to state a claim. Although the Court has some serious reservations as to the merits of the plaintiff's claims, at this point, the Court cannot conclude that it is beyond doubt that the plaintiff will be able to prove a violation of *Section 1* and thus Scotts' motion to dismiss must be denied.

An appropriate Order follows.

ORDER

AND NOW, this 1st day of June, 2006, upon consideration of the motion to dismiss filed by the Scotts Company (Docket No. 5), the plaintiff's opposition and Scotts' reply, as well as arguments presented at a hearing held on March 18, 2005, IT IS HEREBY ORDERED that Scotts' motion to dismiss is DENIED for the reasons set forth in a memorandum of this date.

The Court will hold a telephone conference [*20] with counsel on Monday, June 26, 2006 at 11:00 a.m. to discuss the scheduling of this case. Counsel for the plaintiff shall initiate the call. Judge McLaughlin's chambers telephone number is 267-299-7600. Prior to the telephone conference the parties shall attempt to reach an agreement regarding a schedule for discovery and dispositive motions.

BY THE COURT:

/s/

MARY A. McLAUGHLIN, J.

EXHIBIT D

Not Reported in F.Supp.2d, 2000 WL 34213890 (D.N.J.)
(Cite as: Not Reported in F.Supp.2d)

H

Briefs and Other Related Documents
Only the Westlaw citation is currently available.

United States District Court,D. New Jersey.
WARNER LAMBERT CO., Plaintiff,
v.
PUREPAC PHARMACEUTICAL CO. and Faulding Inc., Defendants.
PUREPAC PHARMACEUTICAL CO. and Faulding Inc., Plaintiffs,
v.
WARNER LAMBERT CO. and Godecke Aktiengesellschaft, Defendants.
No. Civ.A. 98-02749(JCL), Civ.A. 99-05948(JCL), Civ.A. 00-02053(JCL).

Dec. 22, 2000.

John J. Francis, Jr., Drinker, Biddle & Reath, Florham Park, NJ, for plaintiff.
Arnold B. Calmann, Saiber, Schlesinger, Satz & Goldstein, Esqs., Newark, NJ, for defendants.

OPINION

LIFLAND, J.

***1** Presently before the Court are the following three motions in cases involving Plaintiff Warner Lambert Co. ("Warner-Lambert") and Defendants Purepac Pharmaceutical Co. and Faulding Inc. (collectively referred to as "Purepac").

Docket No. 99-05948: Warner-Lambert moves, pursuant to Rule 12(b)(6), to dismiss Purepac's counterclaims alleging antitrust violations and unfair competition. That motion will be denied.

Docket No. 98-02749: Warner-Lambert moves for partial summary judgment dismissing Purepac's counterclaim alleging unfair competition, and in the alternative, Warner-Lambert moves to bifurcate the patent infringement claims from the unfair competition claims. That motion will be denied in part and granted in part.

Docket No. 00-02053: Warner-Lambert moves to dismiss Purepac's complaint which seeks a declaratory judgment of non-infringement. That motion will be granted.

BACKGROUND

A. First Lawsuit (98-2749):

The following facts are undisputed unless otherwise noted. Warner-Lambert discovered gabapentin in the mid-1970's. Warner-Lambert learned that gabapentin was useful in preventing and limiting epileptic seizures. In 1979, Warner-Lambert obtained U.S. Patent No. 4,087,544 (" '544 patent") covering the use of gabapentin to treat epilepsy. That patent expired on January 16, 2000.

On January 15, 1992, Warner-Lambert submitted a New Drug Application ("NDA") to the FDA for the use of gabapentin to treat epilepsy. On December 30, 1993, the FDA approved the NDA. According to the FDA's required labeling, gabapentin is useful for "adjunctive therapy in the treatment of partial seizures with and without secondary generalization in adults with epilepsy." The tradename used by Warner-Lambert for gabapentin is Neurontin.

In the late 1980's, Warner-Lambert discovered that gabapentin could be useful in slowing or preventing neurodegeneration. On January 28, 1992, Warner-Lambert received U.S. Patent No. 5,084,479 (" '479 patent") claiming the use of gabapentin to treat neurodegenerative diseases. That patent expires on January 2.2010. The '479 patent's dependent claims describe a method wherein the neurodegenerative disease is stroke, Alzheimer's disease, Huntington's disease, Amyotrophic Lateral Sclerosis (A.L.S.), and Parkinson's disease.

Before the late 1980's, gabapentin was known to exist in two principal forms: (1) an anhydrous form

where no water is associated with the gabapentin molecules and (2) a hydrated form where some water is associated with the gabapentin molecules. Only two hydrated forms were known: (1) two gabapentin molecules associated with each molecule of water and (2) four gabapentin molecules associated with each molecule of water.

In the late 1980's, two of Warner-Lambert's chemists discovered a new, previously-unknown form, where each gabapentin molecule is associated with one molecule of water. This monohydrate is very crystalline and could be purified to a high degree. After purification, the monohydrate can be readily converted back to the anhydrous form, containing no water. Warner-Lambert received U.S. Patent No. 4,894,476 (" '476 patent") on January 16, 1990 claiming the new monohydrate. The '476 patent expires on May 2, 2008.

***2** In early 1994, after receiving FDA approval for the use of gabapentin to treat epilepsy, Warner-Lambert began marketing gabapentin under the Neurontin label. Doctors also began to use Neurontin to treat neurodegenerative conditions such as Parkinson's disease, A.L.S. and neuropathic pain, even though it had not been approved by the FDA for such use. Increased awareness of these other uses of Neurontin led to significant sales for non-epilepsy uses. Today, more than 78% of Neurontin prescriptions are written for indications other than epilepsy, including the treatment of neuropathic pain and neurodegenerative diseases.

In the middle of 1997, Purepac began to look at the feasibility of selling a generic version of Neurontin. In conducting its feasibility studies, Purepac contacted two gabapentin suppliers. Plantex and Recon. Purepac settled on Plantex and the samples used to support its eventual application to the FDA were made with Plantex gabapentin.

On March 30, 1998, after completing work on its generic gabapentin. Purepac submitted its Abbreviated New Drug Application to the FDA. With this submission, Purepac was required to certify as to each patent covering gabapentin, which are listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"). The Orange Book contains all the patents that a pioneer manufacturer listed on its NDA to the FDA. As to Warner-Lambert's '544 patent (use of gabapentin to treat epilepsy). Purepac certified that it did not intend to market its generic gabapentin until that patent expired. Purepac also certified that Warner-Lambert's '476 gabapentin monohydrate patent would not be infringed by Purepac's manufacture and sale of generic gabapentin. Purepac did not certify as to Warner-Lambert's '479 patent (use of gabapentin to treat neuro-degenerative diseases). Alternatively, Purepac filed a statement of "inapplicable use."

After its certifications to the FDA. Purepac sent notice to Warner-Lambert. The Notice was received on June 1, 1998, and informed Warner-Lambert of Purepac's position regarding the '476 monohydrate patent. On July 14, 1998, Warner-Lambert brought this action alleging infringement of the '476 and '479 patents.

Purepac moved for summary judgment. On August 25, 1999, this Court denied the motion due to unresolved discovery issues surrounding the '476 patent and due to genuine issues of material fact as to whether Purepac would knowingly and actively induce infringement of the '479 patent.

B. Second Lawsuit (99-5948):

Purepac filed a subsequent Abbreviated New Drug Application with the FDA for a generic version of gabapentin in tablet form as opposed to the capsule form involved in 98-2749. Thereafter, Purepac certified that Warner-Lambert's '476 gabapentin monohydrate patent would not be infringed by Purepac's manufacture and sale of generic gabapentin.. After receiving notice on November 8, 1999, Warner-Lambert brought this second action against Purepac, also alleging infringement of the '476 and '479 patents.

***3** Purepac filed counterclaims against Warner-Lambert alleging, in pertinent part, violation of the antitrust laws and unfair competition. The counterclaims allege the following facts: Warner-Lambert fraudulently listed the '476

and '479 patents in the NDA to the FDA for approval of gabapentin anhydrous, under the brand name Neurontin. By listing these patents in the NDA, Warner-Lambert forced the FDA to include the patents in the Orange Book. Any generic gabapentin manufacturer is prevented from applying for an ANDA without listing the patents contained in the Orange Book and giving notice to the patent holder. Once the required notice is given, the pioneer manufacturer has immediate authorization to institute infringement litigation even though the ANDA claims that there is no infringement. According to Purepac, Warner-Lambert listed the '476 patent even though the gabapentin monohydrate covered by the '476 patent was not used at any point during the production of Neurontin. The counterclaim further alleges that Warner-Lambert should not have listed the '479 patent because the labeling authorization for Neurontin permits treatment only for illnesses related to epilepsy.

Purepac contends that subsequent to this Court's denial of summary judgement in 98-2749, the capsule litigation, discovery has revealed that Purepac's form of gabapentin does not contain gabapentin monohydrate, thereby negating any possible infringement of the '476 patent.

C. Litigation Surrounding Patent '482 (00-2053 and 00-2931):

On April 25, 2000, Warner-Lambert was issued Patent 6,054,482 (" '482 patent") for "Lactam-Free Amino Acids." This patent covers gabapentin formulas which are low in lactam impurities. Purepac alleges that Warner-Lambert threatened to sue Purepac for infringement of the '482 patent based on the earlier ANDA applications to market generic gabapentin capsules and tablets.

There is a factual dispute as to the actual point at which the '482 patent was listed in the FDA Orange Book. The record indicates that Warner-Lambert submitted the '482 patent information to the FDA on April 25, 2000 via telecopier. However, Purepac provides the Declaration of Arona Same stating that she was unable to find the '482 patent listed in the Orange Book until May 16, 2000. On April 28, 2000 Purepac filed suit in this court seeking a declaratory judgment of non-infringement and invalidity of the '482 patent. *Purepac v. Warner-Lambert,* No. 00-02053(JCL). After locating the '482 patent in the Orange Book, Purepac amended its ANDA applications for both gabapentin tablets and capsules to include Paragraph IV certifications that Purepac's products do not infringe upon the '482 patent. The record indicates that Warner-Lambert received official notice of the Paragraph IV certifications on June 14, 2000. On August 28, 2000 Warner-Lambert filed a motion in this court to dismiss Purepac's complaint for lack of subject matter jurisdiction under Rule 12(b)(1) and for failure to state a claim under Rule 12(b)(6).

***4** On July 15, 2000, Warner-Lambert filed a complaint against Purepac in this Court alleging infringement of the '482 patent. *Warner-Lambert v. Purepac,* No. 00-02931(JCL).

I. Warner-Lambert's Motion to Dismiss Purepac's Counterclaims of Antitrust Violations in Docket No. 99-05948.

STANDARD OF REVIEW

A. Motion to Dismiss under 12(b)(6):

In deciding a motion to dismiss a counterclaim under Federal Rule of Civil Procedure 12(b)(6), all allegations in the counterclaim must be taken as true and viewed in the light most favorable to the counterclaimant. *See Warth v. Seldin,* 422 U.S. 490, 501, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975); *Trump Hotels & Casino Resorts, Inc., v. Mirage Resorts Inc. .,* 140 F.3d 478, 483 (3d Cir.1998); *Robb v. Philadelphia,* 733 F.2d 286, 290 (3d Cir.1984). A court may consider only the counterclaim, exhibits attached to the counterclaim, matters of public record, and undisputedly authentic documents if the counterclaims are based upon those documents. *See Pension Benefit Guar. Corp. v. White Consol., Indus.,* 998 F.2d 1192, 1196 (3d Cir.1993). If, after

viewing the allegations in the light most favorable to the counterclaimant, it appears beyond doubt that no relief could be granted "under any set of facts which could prove consistent with the allegations," a court shall dismiss a counterclaim for failure to state a claim. *Hishon v. King & Spalding,* 467 U.S. 69, 73, 104 S.Ct. 2229, 81 L.Ed.2d 59 (1984); *Zynn v. O'Donnell,* 688 F.2d 940, 941 (3d Cir.1982).

Furthermore, "[I]n antitrust cases, where 'the proof is largely in the hands of the alleged conspirators.' dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Hospital Building Co. v. Trustees of Rex Hospital,* 425 U.S. 738, 746, 96 S.Ct. 1848, 48 L.Ed.2d 338 (1976) (quoting *Poller v. Colombia Broadcasting,* 368 U.S. 464, 473, 82 S.Ct. 486, 7 L.Ed.2d 458 (1962)). "The liberal approach to the consideration of antitrust complaints is important because inherent in such an action is the fact that all details and specific facts relied upon cannot properly be set forth as part of the pleadings." *See Lucas Indus. v. Kendiesel, Inc.,* 1995 WL 350050, at *2 (D.N.J. June 9, 1995). This court must take " mere conclusions of the pleader" into account when deciding whether a claim for relief is stated. *See id.* at *2 (quoting *United States v. Employing Plasterers' Assn.,* 347 U.S. 186, 188 (1954)).

However, courts have determined that "the heavy costs of modern federal litigation, especially antitrust litigation, and the mounting caseload pressure on the federal courts," militate in favor of requiring some reasonable particularity in pleading violations of the federal antitrust laws." *See Sutliff, Inc. v. Donovan, Co.,* 727 F.2d 648, 654 (7th Cir.1984); *Garshman v. Universal Resources Holding, Inc.,* 641 F.Supp. 1359, 1367 (D.N.J.1986) .

DISCUSSION

Warner-Lambert argues that Purepac's counterclaims of antitrust violation should be dismissed for failure to state a claim because Warner-Lambert's claims of patent infringement are protected under the *Noerr-Pennington* doctrine. Furthermore, Warner-Lambert argues that Purepac lacks standing to bring a claim for antitrust injury.

A. Immunity under Noerr-Pennington Doctrine

1. Sham Litigation

***5** Purepac claims that Warner-Lambert initiated patent infringement litigation for the sole purpose of forestalling Purepac's ability to enter the gabapentin market. Warner-Lambert claims protection under the *Noerr-Pennington* doctrine of immunity for activities petitioning the government, including access to the courts for redress of grievances. *See Eastern R.R. President Conference v. Noerr Motor Freight,* 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961). Under this doctrine, Warner-Lambert would be immune from antitrust liability for the anti-competitive effects of its patent infringement litigation. *See Professional Real Estate Investors, et. al. v. Columbia Pictures Indus., Inc., et. al.,* 508 U.S. 49, 60, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993). However, there is an exception to this immunity when the patent infringement case is considered "sham" litigation, i.e. instituted for the sole purpose of precluding competition.

The Supreme Court has established the following test for "sham" litigation:
First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr,* and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.'

Id. at 60-61 (quoting *Noerr,* 365 U.S. at 144).

Warner-Lambert argues that, as a matter of law, a patent infringement suit which survives summary judgment cannot be considered "objectively baseless

" within the meaning of the "sham" litigation test. Warner-Lambert relies on *Harris Custom Builders, Inc. v. Hoffmeyer,* 834 F.Supp. 246, 261-62 (N.D.Ill.1993), which held that "[a]n action that is well grounded, factually and legally, to survive a summary judgment is sufficiently meritorious to lead a reasonable litigant to conclude that they had some chance of success on the merits." *Id. Harris Custom Builders* dealt with a case in which summary judgment of non-infringement was denied.

In this case, Warner-Lambert's claims survived summary judgment in the 98-2749 patent infringement action based on Purepac's application for generic gabapentin capsules. Purepac's antitrust counterclaims in 99-5984 are based on the capsule litigation in 98-2749, in combination with the infringement litigation (99-5948) brought by Warner-Lambert after Purepac's application to market generic gabapentin tablets. Therefore, the denial of summary judgment in 98-2749 does not necessarily relate to the asserted basis for antitrust relief.

Moreover, denial of summary judgment denial, in and of itself, cannot deem litigation objectively reasonable without specific examination of the basis for denial of summary judgment. *See Filmtech Corp. v. Hydranautics,* 67 F.3d 931, 938 (Fed.Cir.1995) (citing *Boulware v. Nevada Dep't of Human Resources,* 960 F.2d 793, 798-99 (9th Cir.1992) ("a preliminary success on the merits does not preclude a court from concluding that litigation was baseless"). This Court's August 25, 1999 order denying summary judgment was based in part on unresolved discovery issues involving the '476 patent infringement claim. Consequently, the order, by itself, does not require a finding that Warner-Lambert's 98-2749 litigation was reasonably calculated to elicit a favorable outcome.

***6** As to the '479 patent infringement claim, this Court found that there was sufficient evidence to " create a genuine issue of material fact as to whether Purepac will knowingly and actively induce infringement of Patent '479." The '479 patent claims the use of gabapentin for treatment of neuro-degenerative diseases. However, the record indicates that this is an "off-label" use for Neurontin because the FDA has not approved Neurontin for treatment of neuro-degenerative diseases. Purepac's ANDA for a generic form of gabapentin only claims the method of use for treatment of epilepsy. Consequently, Purepac alleges that Warner-Lambert's claim of '479 patent infringement is merely a "sham" to disguise the anti-competitive goal of preventing Purepac from receiving FDA approval of their ANDA. The mere fact that summary judgment was denied in the 98-2749 litigation does not, in and of itself, preclude Purepac's counterclaims of antitrust violations.

2. Fraudulent Conduct

Purepac further claims that Warner-Lambert does not enjoy *Noerr-Pennington* immunity because Warner-Lambert fraudulently listed Patents '476 and '479 in the Neurontin NDA, which automatically triggered the FDA listing of both patents in the Orange Book. According to Purepac, any generic gabapentin manufacturer is prevented from applying for an ANDA without listing the patents contained in the Orange Book and giving notice to the patent holder, thereby triggering infringement litigation. Under the Hatch-Waxman Act, once a pioneer manufacturer has filed an infringement claim, approval of the generic manufacturer's ANDA is stayed for a period prescribed in 21 U.S.C. 355(c)(3)(C). Purepac argues that Warner-Lambert's fraudulent listing of the '476 and '479 patents in the NDA precluded Purepac's ability to compete in the market.

A counterclaim alleging that a patent infringement plaintiff "obtained patent by knowingly and willfully misrepresenting the facts" will "be sufficient to strip [the plaintiff] of its exemption from the antitrust liability." *Walker Process Equip., Inc. v. Food Machinery and Chemical Corp.,* 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965) . Historically, while regional law has always been applied to antitrust litigation, the Federal Circuit has held that "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from antitrust law is to be decided as a question of Federal Circuit Law." *Nobelpharma v.*

Implant Innovations, 141 F.3d 1059, 1067-68 (Fed.Cir.1998).

Warner-Lambert first argues that Purepac incorrectly implicates the fraud exception to *Noerr* because Purepac did not sufficiently allege fraud in the counterclaim. Purepac did not explicitly mention the word "fraud." However, in *Nobelpharma* the Federal Circuit defined the fraud exception to *Noerr-Pennington* immunity as "a knowing, willful and intentional act, misrepresentation, or omission." *Nobelpharma,* 141 F.3d at 1070. Purepac alleges that "Warner Lambert caused the '476 patent to be listed in the Orange Book knowing that it does not cover gabapentin sold under the trade name Neurontin ... Warner-Lambert improperly caused the '476 patent to be listed in the Orange Book. Warner Lambert's motive and intent in causing the '476 patent to be listed in the Orange Book was to forestall competition in the market for Gabapentin." *See* Answer and Counterclaim. ¶ 63-64. Purepac makes the same assertions regarding the '479 patent. *See* Answer and Counterclaim, ¶ 66-67. Purepac adequately alleges that Warner-Lambert knowingly made misrepresentations to the FDA with the specific intent to prevent competition.

*7 Warner-Lambert next argues that Purepac does not apply the current law. Warner-Lambert cites *Armstrong Surgical Center, Inc. v. Armstrong County Mem. Hosp.,* 185 F.3d 154, 162 (3rd Cir.1999). *cert. denied,* 530 U.S. 1261, 120 S.Ct. 2716, 147 L.Ed.2d 982 (U.S. June 26, 2000) for the proposition that "liability for injuries caused by state action is precluded even where the action did so by bribery, deceit or other wrongful conduct that may have affected the decision making process." Warner-Lambert argues that even if it was fraudulent in listing the '476 and '479 patents, it is protected from antitrust liability because the FDA, as a state actor, controls the Orange Book and requirements for ANDA applicants.

However, the *Armstrong* case does not apply to this matter. Although *Armstrong* involves a private party who deceived a state department, the department also conducted independent investigations and provided for two separate reviews of the decision. *See id.* at 163. This differs from a situation where the alleged deceit and fraudulent conduct is directed at a regulatory agency which does not conduct independent investigations. Consequently, the *Armstrong* court drew a distinction from a typical patent case:

The decision making process [in a typical patent situation] was an ex parte one in which the Patent Office was wholly dependent on the applicant for the facts. While the Patent Office can determine the prior act from its own records, it effectively and necessarily delegates to the applicant the factual determinations underlying the issuance of a patent. Accordingly, when the applicant has submitted false factual information, the state action is dependent on financially interested decision making.

Id. at 164.

In this case, Purepac contends that the FDA relies solely upon the NDA applicant's information when listing patents in the Orange Book. *See* Answer and Counterclaim ¶ 47. Therefore, the FDA would be forced to rely upon fraudulent misrepresentations by Warner-Lambert. Viewing the allegations in the counterclaim in the light most favorable to Purepac, discovery could demonstrate fraudulent conduct by Warner-Lambert, thereby removing immunity from antitrust liability.

B. Antitrust Standing

Warner-Lambert argues that Purepac's counterclaims for violations of the Sherman Act must be dismissed because Purepac does not have standing to assert antitrust injury. The United Supreme Court has listed the appropriate guidelines for determining whether antitrust standing exists. *See Associated Gen. Contractors v. California State Council of Carpenters,* 459 U.S. 519, 534-45, 103 S.Ct. 897, 74 L.Ed.2d 723 (1983). This Court must decide:

(1) whether there is a causal connection between an antitrust violation and harm to the plaintiff and the defendants intended to cause that harm;

(2) whether the nature of the plaintiff's alleged injury was of the type the antitrust laws were intended to forestall;

(3) the directness or indirectness of the asserted injury;
***8** (4) whether the claim rests on some abstract or speculative measure of harm; and
(5) the strong interest in keeping the scope of complex antitrust trials within judicially manageable limits, avoiding both duplicative recoveries and the complex apportionment of damages.

See Indium Corp. of America v. Semi-Alloys, Inc., 781 F.2d 879, 882 (Fed.Cir.1985) (quoting *Associated Gen. Contractors*, 459 U.S. at 434-45).

These general guidelines have been supplemented by caselaw which focuses on the direct issue in this matter. The specific rules under 21 U.S.C. § 355(j)(5)(B)(iii) ("Hatch-Waxman Act") require a thirty-month stay on FDA approval for a generic pharmaceutical manufacturer's ANDA when the ANDA product becomes involved in patent infringement litigation with the pioneer manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Because "the commencement of litigation automatically delay[s] FDA approval of the generics' proposed drugs." the patent infringement plaintiff has the power to forestall a generic manufacturer's ability to market a product. *See Bristol-Meyers v. Ben Venue Lab.*, 90 F.Supp.2d 540, 544 (D.N.J.2000). Therefore, the generic manufacturer's injury does not merely result from the "structure of a regulated industry," but from the decision of the pioneer manufacturer to bring suit. *See id.* at 545. Consequently, the Supreme Court's requirement for a special "causal connection" and " directness" of injury must be liberally construed when dealing with regulatory conditions under the Hatch-Waxman Act.

In this case. Warner-Lambert instituted the patent infringement cases against Purepac. thereby delaying FDA approval of a generic form of gabapentin in either tablet or capsule form. This decision to delay approval of the ANDA was not left to the discretion of the FDA, so it cannot be attributed to the structure of the regulated industry. Warner-Lambert has exercised its power under Hatch-Waxman to temporarily foreclose Purepac's access to the market for gabapentin. Purepac has alleged a sufficient causal connection between Warner-Lambert's allegedly fraudulent conduct and Purepac's injuries.

Accordingly, this Court finds that Purepac has standing to bring antitrust counterclaims against Warner-Lambert.

II. Warner-Lambert's Motion for Partial Summary Judgment Against Purepac's Unfair Competition Counterclaim, or in the Alternative, Bifurcation of the Patent and Antitrust Claims in Docket No. 98-02749.

STANDARD OF REVIEW

Summary judgment eliminates unfounded claims without recourse to a costly and lengthy trial. *See Celotex Corp. v. Catrett,* 477 U.S. 317, 327, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). However, a court should grant summary judgment only "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Fed.R.Civ.P.* 56(c). The burden of showing that no genuine issue of material fact exists rests initially on the moving party. *See Celotex,* 477 U.S. at 323. A litigant may discharge this burden by exposing "the absence of evidence to support the nonmoving party's case." *Id.* at 325. In evaluating a summary judgment motion, a court must view all evidence in the light most favorable to the nonmoving party. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.,* 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986); *Goodman v. Mead Johnson & Co.,* 534 F.2d 566, 573 (3d Cir.1976).

***9** Once the moving party has made a properly supported motion for summary judgment, the burden shifts to the nonmoving party to "set forth specific facts showing that there is a genuine issue for trial ." *Fed.R.Civ.P.* 56(e); *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 247-48, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). The substantive law determines which facts are material. *Id.* at 248. "

Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Id.* No issue for trial exists unless the nonmoving party can demonstrate sufficient evidence favoring it such that a reasonable jury could return a verdict in that party's favor. *See id.* at 249.

DISCUSSION

A. Partial Summary Judgment

Warner-Lambert moves for summary judgment dismissing Purepac's unfair competition counterclaim. Warner-Lambert makes three arguments in support of summary judgment: A) New Jersey unfair competition claims only encompass the illegal "passing off" of a competitor's product as one's own product. B) Warner-Lambert's patent infringement suits against Purepac are protected under the *Noerr-Pennington* immunity doctrine, and C) Purepac does not have standing to bring the unfair competition claims because Purepac has suffered no injury.

In Part I of this opinion, the Court addressed Warner-Lambert's arguments regarding immunity under *Noerr-Pennington* and Purepac's alleged lack of standing. Warner-Lambert's brief admits the identical nature of the arguments:
In light of the substantial overlap of issues relating to defendants' unfair competition counterclaim in this action and their antitrust and unfair competition counterclaim in [99-5948: capsule litigation], the discussion in Sections B and C [dealing with *Noerr-Pennington* and standing], *infra,* and in Warner-Lambert's memorandum in support of its Fed.R.Civ.P. 12(b)(6) motion to dismiss defendants' antitrust and unfair competition counterclaims in [99-5948: capsule litigation] is *essentially the same.*

Warner-Lambert's Brief at p.12 n. 2. Therefore, this Court will only address Warner-Lambert's first argument which addresses the scope of the New Jersey unfair competition claim.

Warner-Lambert argues that the New Jersey law of unfair competition is limited to the "passing-off" of one's goods as those of a competitor and similar deceptive practices. However, caselaw demonstrates that the unfair competition claim is not as narrow as Warner-Lambert contends.

Warner-Lambert relies on a district court decision which states that "under New Jersey common law, unfair competition encompasses two separate torts: (1) passing off one's goods or services as those of another; and (2) unprivileged imitation." *See Eli Lilly & Co. v. Russel Corp.,* 23 F.Supp.2d 460, 494 (D.N.J.1998). Warner-Lambert argues that Purepac's allegations of unfair competition do not fit into either category because Purepac's allegations are based only on sham litigation and fraudulent submissions of patent information to the FDA.

***10** The Court is inclined to follow the cases relied upon by Purepac. *See Biovail Corp. Int'l v. Aktiengesellschaft,* 49 F.Supp.2d 750 (D.N.J.1999); *Duffy v. Charles Schwab & Co., Inc.,* 97 F.Supp.2d 592 (D.N.J.2000). In *Biovail,* Judge Barry denied the defendants' motion to dismiss plaintiff's claims of unfair competition under New Jersey law because the conduct alleged was "injurious and otherwise unfair, improper and wrongful" and "having found that the conduct alleged by [plaintiff] constitutes, at least on the pleadings, possible antitrust violations, it is fair to say that the conduct states a claim under the much broader common law tort of unfair competition." *Biovail,* 49 F.Supp.2d at 777. In *Duffy,* Judge Cooper emphasized that although the defendant argued that the *Eli Lilly* case stood for the proposition that "only two types of claims may be brought under New Jersey's unfair competition law: (1) passing off, and (2) unprivileged imitation .... [t]he language of *SK & F* and *Eli Lilly* should not be read to limit the reach of New Jersey's unfair competition law to these two torts alone." *Duffy,* 97 F.Supp.2d at 601 n. 8. Accordingly, this Court rejects Warner-Lambert's argument that caselaw narrows the scope of unfair competition claims.

The Restatement (Third) of Unfair Competition suggests a broad range of unfair competition claims:
Certain recurring patterns of objectionable practices form the basis of the traditional categories of liability specifically enumerated in [the

Restatement]. However, *these specific forms of unfair competition do not fully exhaust the scope of statutory or common law liability for unfair methods of competition* .... It is impossible to state a definitive test for determining which methods of competition will be deemed unfair in addition to those included in the categories of conduct described in the preceding Comments. Courts continue to evaluate competitive practices against generalized standards of fairness and social utility. *Judicial formulations have broadly appealed to principles of honesty and fair dealing, rules of fair play and good conscience, and the morality of the marketplace.* The case law, however, is far more circumscribed than such rhetoric might indicate, and courts have generally been reluctant to interfere in the competitive process. An act or practice is likely to be judged unfair only if it substantially interferes with the ability of others to compete on the merits of their products or otherwise conflicts with accepted principles of public policy recognized by statute or common law.

Restatement (Third) of Unfair Competition § 1 cmt. g (1995) (emphasis added). In fact, the comments to the Restatement state that unfair competition claims also apply to "one who interferes by instituting or threatening to institute groundless litigation against a competitor." *Id.* The Restatement explains that the somewhat narrow interpretation of unfair competition claims by caselaw is that "an act or practice is likely to be judged unfair only if it substantially interferes with the ability of others to compete on the merits of their products."

***11** In this case, Purepac alleges Warner-Lambert's conduct has prevented the marketing of a generic form of gabapentin, thereby interfering with Purepac's ability to compete on the merits of the product described in its ANDA. The Court disagrees. Purepac's allegation of fraudulent submissions to the FDA falls within the scope of the unfair competition claims as defined by caselaw and the Restatement. Accordingly, this Court is unwilling to dismiss Purepac's counterclaims based solely on Warner-Lambert's narrow interpretation of New Jersey unfair competition law.

B. Bifurcation

As an alternative to dismissal, Warner-Lambert seeks the bifurcation of the patent claims from the unfair competition claims. Under the Federal Rules of Civil Procedure,

The court, in furtherance of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy, may order a separate trial of any claim, cross-claim, counterclaim, or third-party claim, or of any separate issue or of any number of claims, cross-claims, counterclaims, third-party claims, or issues, always preserving inviolate the right of trial by jury as declared by the Seventh Amendment to the Constitution or as given by a statute of the United States.

Fed. R. Civ. P. 42(b). Generally, "[u]nder Rule 42(b), a district court has broad discretion in separating issues and claims for trial as part of its wide discretion in trial management." *Gardco Manufacturing, Inc. v. Herst Lighting Co.,* 820 F.2d 1209, 1212 (Fed.Cir.1987). The Federal Circuit has approved the "standard practice of separating for trial patent issues and those raised in an antitrust counterclaim." *In re Innotron Diagnostics,* 800 F.2d 1077, 1084 (Fed.Cir.1986); *see also Virginia Panel Corp. v. Mac Panel Co.,* 887 F.Supp. 880, 883-84 (W.D.Va.1995), *aff'd,* 133 F.3d 860 (Fed.Cir.1997); *Hunter Douglas Inc. v. Comfort Corp.,* 44 F.Supp.2d 145, 148 (N.D.N.Y.1999) (finding that the effort "to protect the property rights granted vis-a-vis the patent ... may be viewed as an attempt to extend them, temporally or otherwise, beyond the bounds set by the patent statute ... that allegedly runs afoul of the antitrust laws); *Alarm Device Mfg. Co. v. Alarm Products Intern., Inc.,* 60 F.R.D. 199, 202 (E.D.N.Y.1973) (" More often than not, separate trials of patent validity-infringement claims and misuse-antitrust claims have been found to be salutary"); *Brandt, Inc. v. Crane,* 97 F.R.D. 707, 708 (N.D.Ill.1983) (adopting the "general rule" that separating patent and antitrust issues serves the purposes of convenience, expedience, and economy).

The Federal Circuit has emphasized the necessity of bifurcation of antitrust claims and patent infringement claims because it "will enhance the

parties' right to jury trial by making the issues the jury must consider less complex." *See Innotron,* 800 F.2d at 1086. When deciding a motion to bifurcate, the court should consider "whether one trial or separate trials will best serve the convenience of the parties and the court, avoid prejudice, and minimize expense and delay [and] the major consideration is directed toward the choice most likely to result in a just final disposition of the litigation." *Id.* at 1084.

***12** Purepac argues that bifurcation is inappropriate because "there will be substantial overlap between the issues relevant to the patent and unfair competition claims" based on allegations of Warner-Lambert's fraudulent statements to the FDA and sham litigation. This is probably true. However, caselaw indicates that such overlap supports bifurcation. *See Innotron,* 800 F.2d 1085 (holding that bifurcation was appropriate because defendant's affirmative defenses to the patent infringement case were identical to the antitrust counterclaims and therefore, "if [defendant] prevails at the trial on its affirmative defenses it need not again prove the same issues at the antitrust trial." In *Hunter,* the defendant in a patent infringement case brought antitrust counterclaims against the plaintiff alleging sham litigation. The court ordered bifurcation based on the following analysis:
if [plaintiff] succeeds in its patent infringement action, a significant portion of [defendant's] proof relative to its § 2 [Sherman Act] claim would become irrelevant. This could significantly shorten presentation of [defendant's] antitrust counterclaims. Likewise, during the patent infringement suit, [defendant] would have an opportunity to present its defenses of patent invalidity and inequitable conduct. Resolution of these issues would become the law of the case and also eliminate some of the proof that would otherwise be necessary. Accordingly, the interest of judicial efficiency favors separating the patent issues from those grounded on antitrust principles.

Hunter, 44 F.Supp.2d at 152.

In this case, Purepac's antitrust claims based on sham litigation will be addressed during the patent infringement trial because the outcome of that trial may either support or eliminate Purepac's claim that Warner-Lambert filed an objectively baseless suit.

Purepac also contends that the unfair competition claim based on Warner-Lambert's allegedly fraudulent submission to the FDA, which caused an automatic stay of Purepac's ANDA approval, will be viable regardless of the outcome of the patent infringement trial. However, the patent infringement trial will resolve the scope of the '476 and '479 patents, which is relevant to a determination of whether Warner-Lambert could have engaged in inequitable conduct by listing the patents in the NDA for Neurontin.

Although Purepac relies on a few district court cases denying bifurcation, this Court finds that they are distinguishable. *See ACS Communications, Inc. v. Plantronics, Inc.,* 1995 WL 743726 (N.D.Cal. Dec.1, 1995) (denying bifurcation because the antitrust claim was filed before the patent infringement counterclaim); *General Tel. & Elec. Labs. Inc. v. National Video Corp.,* 297 F.Supp. 981 (N.D.Ill.1968) (denying bifurcation of all counterclaims in a patent infringement case involving counterclaims which alleged *both* antitrust violations *and* new patent infringement claims); *Spectra-Physics Lasers. Inc. v. Uniphase Corp.,* 144 F.R.D. 99 (N.D.Cal.1992) (denying bifurcation of issues of liability and damages).

***13** Therefore, this Court concludes that bifurcation would best serve the interests of justice.

III. Warner-Lambert's Motion to Dismiss Purepac's Complaint Seeking Declaratory Judgment of Non-Infringement under Rule 12(b)(1) and Rule 12(b)(6) in Docket No. 00-02053.

STANDARD OF REVIEW

A defendant may challenge the court's subject matter jurisdiction in two ways. First, defendant may attack the jurisdictional allegations of a complaint on its face. *See Cardio-Medical Ass'n Ltd. v. Crozer-Chester Med. Ctr.,* 721 F.2d 68, 75 (3d Cir.1983) (commenting that the Court in

assessing a Rule 12(b)(1) motion based on [a facial jurisdictional attack] on the pleadings must assume that the allegations contained in the complaint are true and holding that allegations in complaint were sufficient to meet jurisdictional requirement of Sherman Act) (citations omitted). The second way to bring a 12(b)(1) motion is a factual jurisdictional attack, in which case the Court may rely on competent evidence other than the complaint. *See Land v. Dollar,* 330 U.S. 731, 735 n. 4, 67 S.Ct. 1009, 91 L.Ed. 1209 (1947) (noting that "when a question of the District Court's jurisdiction is raised, ... the court may inquire by affidavits or otherwise, into the facts as they exist").

Therefore, unlike a 12(b)(6) motion, in considering a 12(b)(1) motion based on a factual jurisdictional attack to a complaint, "no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims. Moreover, [in defending against a factual jurisdictional attack], the plaintiff will have the burden of proof that jurisdiction does in fact exist." *Mortensen v. First Fed. Savings & Loan Ass'n,* 549 F.2d 884, 891 (3d Cir.1997) (vacating dismissal of Sherman Act claim for lack of subject matter jurisdiction and finding that "a combination of the timing of the factual jurisdictional attack, the plaintiff's having the burden of proof, and the court's having a free hand in evaluating jurisdictional evidence ... can unfairly preclude Sherman Act plaintiffs from reaching the merits of their cases"); *Lang v. Rubin,* 73 F.Supp.2d 448, 450 (D.N.J.1999). "That the district court is free to determine facts relevant to its jurisdiction has long been clear." *Mortensen,* 549 F.2d at 891 n. 16 (citing *Wetmore v. Rymer,* 169 U.S. 115, 18 S.Ct. 293, 42 L.Ed. 682 (1898)). "[D]ismissal for lack of subject matter jurisdiction is not appropriate merely because the legal theory alleged is probably false, but only because the right claimed is 'so insubstantial, implausible, foreclosed by prior decisions of this Court, or otherwise completely devoid of merit as not to involve a federal controversy.' " *Growth Horizons, Inc. v. Delaware County, Pa.,* 983 F.2d 1277, 1280-81 (3d Cir.1993) (reversing dismissal for lack of subject matter jurisdiction on Fair Housing Act claim) (quotation omitted). "The threshold to withstand a motion to dismiss under Fed.R.Civ.P. 12(b)(1) is thus lower than that required to withstand a Rule 12(b)(6) motion." *Lunderstadt v. Colafella,* 885 F.2d 66, 70 (3d Cir.1989) (quotation omitted).

DISCUSSION

1. Rule 12(b)(1) Motion to Dismiss for Lack of Subject Matter Jurisdiction

***14** Warner-Lambert argues that Purepac has violated the Declaratory Judgment Act by filing the instant complaint as a mere pre-emptive strategy to avoid the statutory provisions of the Hatch-Waxman Act.

The Declaratory Judgment Act provides:
[i]n a case of actual controversy within its jurisdiction, except with respect to Federal taxes ..., any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewed as such.

§ 28 U.S.C. 2201.

The Federal Circuit has set standards regarding jurisdiction of declaratory judgment claims against a patentee. *See Fina Research v. Baroid Ltd.,* 141 F.3d 1479, 1481 (Fed.Cir.1998); *Genentech, Inc. v. Eli Lilly & Co.,* 998 F.2d 931, 936-37 (Fed.Cir.1993). "We regularly review whether there is jurisdiction over an action seeking a declaratory judgment." *Fina,* 141 F.3d at 1481; *see generally Super Sack Mfg. Corp. v. Chase Packaging Corp.,* 57 F.3d 1054, 1058-59 (Fed.Cir.1995). In *Fina,* the Federal Circuit held:
[t]o determine whether there is an actual controversy in declaratory judgment actions involving allegations of patent non-infringement, invalidity, or unenforceability, we apply a two-prong inquiry: There must be both (1) an explicit threat or other action by the patentee, which

creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

Fina, 141 F.3d at 1481 (citing *Super Sack,* 57 F.3d at 1058 (quoting *BP Chems. Ltd. v. Union Carbide Corp.,* 4 F.3d 975, 978 (Fed.Cir.1993)). *See also Genentech,* 998 F.2d at 936-37. Although the court has discretion to decide whether subject matter jurisdiction exists, "the exercise of discretion in [deciding to entertain] a declaratory judgment must have a basis in sound reason" and conform to the established rule. *Genentech,* 998 F.2d at 936.

A. The Hatch-Waxman Act

The Hatch-Waxman Act was enacted to regulate the interplay between pioneer drug manufacturers and generic drug manufacturers. When filing an NDA, the pioneer applicant must file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted. *See* 21 U.S.C. 355(b)(1). Upon approval of the NDA, any claimed patents for the approved drug are published in the Orange Book. *See* 21 U.S.C. 355(j)(7)(A)(iii).

A generic manufacturer of the original drug approved by the NDA must file an ANDA with the FDA. The ANDA applicant must also certify as part of the application that for each patent listed: (I) such patent information has not been already filed; (II) such patent has expired; (III) the date on which such patent will expire; or (IV) such patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug. *See* 21 U.S.C. 355(j)(2)(A)(vii). An ANDA applicant making a Paragraph IV certification must provide notice to the owner of the patent and the holder of the approved NDA for the listed drug, stating that it has submitted an ANDA and including a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." § 21 U.S.C. 355(j)(2)(B)(ii). Furthermore, a Paragraph IV certification creates a cause of action for patent infringement. If, within 45 days of receiving notice, the patent owner sues the ANDA applicant for patent infringement, the ANDA approval is essentially stayed for 30 months. *See* 21 U.S.C. 355(j)(5)(B)(iii).

***15** The statute also provides that during the 45-day period after the ANDA applicant gives notice of its Paragraph IV certification, "no action may be brought under section 2201 of Title 28 for a declaratory judgment with respect to the patent." § 21 U.S.C. 355(j)(5)(B)(iii)(III).

The legislative history of the Hatch-Waxman Act states that:
No action for a declaratory judgment regarding the patent at issue may be brought before the expiration of the 45 day period commencing with the provision of notice of the certification of patent invalidity or non-infringement. After the 45 day period, any suit for declaratory judgment regarding the patent at issue must be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

H.R. Rep. 98-857(I), 98th Cong., 2ND Sess.1984. at 47.

The purpose of the forty-five day period is to provide the patentee time in which to bring suit for patent infringement. Although the legislative history allows for a declaratory judgment action after the forty-five day period, there is no indication that Congress meant to permit the alleged infringer to bring a declaratory judgment action before the commencement of the forty-five day period.

Purepac contends that the forty-five day period during which a declaratory judgment action is prohibited did not commence until Purepac filed the Paragraph IV certification and notice. Because the FDA was late in filing the '482 patent in the " Orange Book." Purepac did not know whether it was necessary to file the Paragraph IV certification for two weeks. Before that two-week period expired, and before Purepac filed its Paragraph IV certification. Purepac brought suit for declaratory

judgment against Warner-Lambert. This Court rejects Purepac's argument that its declaratory judgment action is permitted.

The record indicates that Warner-Lambert filed Patent '482 with the FDA (for purposes of listing in the Orange Book) immediately after receiving approval from the U.S. Patent Office on April 25, 2000. Purepac claims that the '482 patent was not listed in the Orange Book until May 16, 2000. However, any delay in the actual listing of patents in the Orange Book is not attributable to Warner-Lambert because the FDA controls the Orange Book. This Court is not in a position to modify the clear intent of the Hatch-Waxman Act because of delays attributable to the FDA's clerical system. 21 U.S.C. 355(j)(5)(B)(iii)(III) is meant to give the patentee a limited period of time to decide whether to bring suit for infringement before a declaratory judgment action can be instituted by a generic drug manufacturer.

In this case, Warner-Lambert was issued the '482 patent on April 25, 2000 and Warner-Lambert submitted the patent information to the FDA on that same day. Purepac became aware of the '482 patent and Purepac filed a declaratory judgment action on April 28, 2000. Purepac alleges that the action was properly filed because the '482 patent had not yet been listed in the Orange Book. Purepac did not amend their generic gabapentin ANDA until after May 16, 2000 and Warner-Lambert did not receive Purepac's Paragraph IV certification until June 14, 2000.

***16** After review of the Hatch-Waxman Act, this Court finds that Congress' dominant intent was to create a thirty-month period during which a pioneer manufacturer could be free from generic competition if it started suit to determine whether a generic manufacturer has infringed an existing patent. This period is triggered by the filing of infringement litigation by the pioneer manufacturer. The suit itself is triggered by the Paragraph IV certification and notice submitted by the generic manufacturer. Once a Paragraph IV certification is made, a suit seeking a declaratory judgment of non-infringement and/or invalidity should be discontinued. Congress' secondary intent under the Hatch-Waxman Act was to establish a sequential series of events based on the assumption that the following would occur in this order: patent, NDA. ANDA and Paragraph IV certification. However, the facts in this case did not occur in the temporal sequence assumed by the Hatch-Waxman Act. In choosing which Congressional intent to enforce, this Court chooses the broader intent because the thirty-month moratorium is more critical to the Congressional scheme than the procedural sequence of events. The Court further notes that infringement litigation has already commenced on the '482 patent . Accordingly, the appropriate resolution is to dismiss the declaratory judgment action.

Caselaw offers minimal guidance as to whether generic drug companies can file declaratory judgment claims before the FDA lists the patent in the Orange Book. Both Purepac and Warner Lambert rely on different theories espoused in *Ben Venue Lab., Inc. v. Novartis Pharm. Corp.,* 10 F.Supp.2d 446, 451-52, (denying a motion to dismiss complaint for lack of subject matter jurisdiction). In *Ben-Venue,* the alleged infringing plaintiff filed a claim seeking a declaratory judgment that one of the defendant's patents was improperly listed in the Orange Book because the defendant deceived the FDA. Although this claim was filed during the forty-five day period set forth in the Hatch-Waxman Act, the court permitted the claim. The court reasoned that 21 U.S.C. 355(j)(5)(B)(iii)(III) "is limited to declaratory judgment actions ... aimed solely at the narrow patent issues of infringement and invalidity." *Id.* at 451.

In this case, Purepac seeks a declaratory judgment that Warner-Lambert's '482 patent is invalid and Purepac's generic form of gabapentin does not infringe. This is the exact type of claim that the Hatch-Waxman Act prohibits before the expiration of the forty-five day period.

The Federal Circuit has offered some guidance in the construction of the Hatch-Waxman Act in *DuPont Merck Pharm. Co. v. Bristol-Meyers Squibb Co.,* 894 F.Supp. 804 (D.Del.1995), *aff'd* 62 F.3d 1397 (Fed.Cir.1995). In *DuPont,* the Federal Circuit affirmed the lower court's dismissal of

plaintiff's complaint seeking a declaratory judgment of patent invalidity and non-infringement. The plaintiff, a generic drug manufacturer, had not filed a Paragraph IV certification or given notice to defendant regarding patents which had an extended expiration date due to the Uruguay Round Agreement Acts ("URAA"). The lower court held that "an actual controversy for purposes of the Declaratory Judgment Act will only occur upon the filing of the appropriate paragraph IV certification by [plaintiff] with the FDA." *See Dupont,* 894 F.Supp. at 809. In affirming this decision, the Federal Circuit held that the special protections of the URAA did not insulate an alleged patent infringer from following the necessary steps under 21 U.S.C. 355(j)(5)(B)(iii)(III). *See id.*

***17** Similar to the *DuPont* court's reasoning, this Court is not prepared to let the filing methods of the FDA interfere with the purpose and intent of the Hatch-Waxman Act.

B. The First-Filed Rule

Purepac argues that this Court cannot dismiss its suit for declaratory judgment by application of the first-filed rule. The Court of Appeals for the Third Circuit has adopted the "first-filed rule" which applies to parallel cases filed in separate district courts. *See EEOC v. University of Pa.,* 850 F.2d 969, 971 (3d. Cir.1988): *Crosley Corp. v. Hazeltine Corp.,* 122 F.2d 925, 929 (3d Cir.1941), *cert. denied.* 315 U.S. 813, 62 S.Ct. 798, 86 L.Ed. 1211 (1942). "In all cases of federal concurrent jurisdiction, the court which first has possession of the subject must decide it." *Crosley Corp. v. Hazeltine Corp.,* 122 F.2d 925, 929 (3d Cir.1941) (quoting *Smith v. McIver,* 22 U.S. (9 Wheat.) 532, 6 L.Ed. 152 (1824)), *cert. denied,* 315 U.S. 813, 62 S.Ct. 798, 86 L.Ed. 1211 (1942). Consequently, trial judges may exercise their discretion to enjoin subsequent prosecution of "similar cases ... in different federal district courts." *EEOC,* 850 F.2d at 971.

Although the first-filed rule gives the trial court broad discretion. Third Circuit precedent has established certain exceptions to the application of the rule, including forum-shopping, bad faith, and inequitable conduct. *See EEOC,* 850 F.2d at 971. " We emphasize, however, that invocation of the rule will usually be the norm, not the exception. Courts must be presented with exceptional circumstances before exercising their discretion to depart from the first-filed rule." *Id.* at 979.

Purepac relies on *Genentech Inc. v. Eli Lilly & Co.,* 998 F.2d 931 (Fed.Cir.1993), where the court applied the first-filed rule to patent litigation and rejected the reasoning of *Tempco v. Electric Heater Corp. v. Omega Eng'g Inc.,* 819 F.2d 746 (7th Cir.1987) (holding that the first-filed rule does not apply to trademark cases). In applying the first-file rule to patent litigation, the *Genentech* court gave the following rationale:

[s]uch a rule [in *Tempco*] would automatically grant the patentee the choice of forum, whether the patentee had sought-or sought to avoid-judicial resolution of the controversy. This shift of relationship between litigants is contrary to the purpose of the Declaratory Judgment Act to enable a person caught in controversy to obtain resolution of the dispute, instead of being forced to await the initiative of the antagonist.... We prefer to apply in patent cases the general rule whereby the forum of the first-filed case is favored, unless considerations of judicial and litigant economy, and the just and effective disposition of disputes, require otherwise.

Id. at 937. In relation to patent cases, the first-filed rule is used only as protection against a patentee's ability to forum-shop. However, in this case the suit for declaratory judgment and the litigation of patent infringement claims are reciprocal cases which are both filed in this Court. Therefore, forum selection is not an issue.

***18** Moreover, the *Genentech* decision differs from the immediate case because the *Genentech* decision dealt with DNA technology which was not subject to FDA regulations. Therefore, in *Genentech,* there was no statutory regulation analogous to the Hatch-Waxman Act which prohibited suit. Accordingly, this Court finds that subject matter jurisdiction is lacking over Purepac's claim for a declaratory judgment.

2. Motion to Dismiss for Failure to State a Claim

Warner-Lambert seeks to dismiss Purepac's complaint for failure to state a claim. Because this Court holds that subject matter jurisdiction is lacking over Purepac's declaratory judgment complaint, due to the Hatch-Waxman Act. Warner Lambert's 12(b)(6) motion to dismiss the complaint need not be addressed.

I. Docket No. 99-05948

For the reasons set forth in the accompanying opinion IT IS on this *22nd* day of December, 2000 ORDERED that Warner Lambert's motion to dismiss Purepac's counterclaims three through five is denied.

II. Docket No. 98-02749

For the reasons set forth in the accompanying opinion IT IS on this *22nd* day of December, 2000 ORDERED that Warner Lambert's motion to dismiss Purepac's counterclaims alleging unfair competition is denied; and it is further

ORDERED that Warner Lambert's motion to bifurcate the patent infringement claims from the unfair competition counterclaims is granted.

III. Docket No. 00-02053

For the reasons set forth in the accompanying opinion IT IS on this *22nd* day of December, 2000 ORDERED that Warner Lambert's motion to dismiss Purepac's complaint seeking a declaratory judgment is granted.

D.N.J.,2000.
Warner Lambert Co. v. Purepac Pharmaceutical Co.
Not Reported in F.Supp.2d, 2000 WL 34213890 (D.N.J.)

Briefs and Other Related Documents (Back to top)

• 2:00CV02053 (Docket) (Apr. 28, 2000)

END OF DOCUMENT


EXHIBIT E

Slip Copy, 2006 WL 1431214 (D.Del.), 2006-1 Trade Cases P 75,282
(Cite as: Slip Copy)

H
Briefs and Other Related Documents

United States District Court,D. Delaware.
In re: INTEL CORP. MICROPROCESSOR ANTITRUST LITIGATION
Phil PAUL, on behalf of himself and all others similarly situated, Plaintiffs,
v.
INTEL CORPORATION, Defendant.
No. MDL 05-1717-JJF, Civ.A. 05-485-JJF.[FN1]

FN1. The two Motions under consideration in this Memorandum Opinion were originally filed in *Wiles v. Intel,* Civil Action No. 05-914-JJF, and *Chance v. Intel,* Civil Action No. 06-265-JJF, which were consolidated into the above captioned action by the Court's Memorandum Order dated April 18, 2006 (D.I.51).

May 22, 2006.

B.J. Wade, of Glassman, Edwards, Wade & Wyatt, P.C., Memphis, Tennessee, William M. Audet, Michael A. McShane, and Ryan M. Hagan, of Alexander, Hawes & Audet LLP, San Jose, California, for Plaintiff Cory Wiles, of counsel.
Rex A. Sharp, and Barbara C. Frankland, of Gunderson, Sharp & Walke, L.L.P., Prairie Village, Kansas, for Plaintiff Marvin D. Chance, Jr.
Jef Feibelman, and Mary Hale, of Burch, Porter & Johnson, PLLC, Memphis, Tennessee, Tim J. Moore , and Robert W. Coykendall, of Morris Laing, Wichita, Kansas, David M. Balabanian, Christopher B. Hockett, and Joy K. Fuyuno, of Bingham McCutchen LLP, San Francisco, California and Richard A. Ripley, and Gregory F. Wells, of Bingham McCutchen LLP, Washington, D.C., for Defendants, of counsel.

MEMORANDUM OPINION

FARNAN, J.
***1** Pending before the Court are Plaintiffs' Motions To Remand (Civ. Action No. 05-914, D.I. 23; Civ. Action No. 06-265, D.I. 33). Plaintiff Cory Wiles (" Wiles") requests the Court to remand his case to the Circuit Court of Shelby County, State of Tennessee. Plaintiff Marvin D. Chance ("Chance") requests the Court to remand his case to the District Court of Seward County, Kansas. Both Plaintiffs base their Motions on the grounds that this Court lacks subject matter jurisdiction. For the reasons discussed, the Court will deny Plaintiffs' Motions.

BACKGROUND

On June 27, 2005, Advanced Micro Devices, Inc. (" AMD") filed a Complaint against Defendant Intel Corporation ("Intel") in this Court alleging antitrust law violations, under the Sherman Act and California state law, involving Intel's domination of the market for x86 microprocessors. That Complaint was followed in rapid succession by the filing against Intel of at least seventy-three class action, antitrust complaints, all of which borrowed liberally from AMD's Complaint. Almost all of the class action suits were originally filed in Federal District Courts. Plaintiffs' Complaints were filed in the Circuit Court of Shelby County, State of Tennessee and the District Court of Seward County, Kansas.

On August 18, 2005, Wiles filed a First Amended Complaint. (*See* Civ. Action No. 05-914, D.I. 24, Ex. A.) Later that same day, Intel filed a Notice of Removal (Civ. Action No. 05-914, D.I. 21, Attachment 1) in the United States District Court for the Western District of Tennessee, Western Division. On September 2, 2005, Wiles filed his Motion To Remand in the Western District of Tennessee. On December 6, 2005, the Judicial Panel on Multidistrict Litigation issued an Order transferring Wiles's case and twenty other related class actions to this Court. (Civ. Action No. 05-914,

D.I. 21, Attachment 37.)

Chance filed his Complaint on August 22, 2005. On October, 3, 2005, Intel filed a Notice Of Removal in the United States District Court for the District of Kansas. On November 2, 2005, Chance Filed his Motion To Remand in the District of Kansas. On April 12, 2006, the Judicial Panel on Multidistrict Litigation issued an Order transferring Chance's case to this Court. (Civ. Action No. 06-265, D .I. 30, Attachment 55.)

DISCUSSION

Plaintiffs contend that this Court should remand their cases to the state courts for lack of jurisdiction, because the aggregated amounts in controversy are less than $5,000,000. Under the Class Action Fairness Act of 2005, ("CAFA"), Pub.L. No. 109-2, 119 Stat. 4 (2005), this Court has jurisdiction over a purported class action where the amount in controversy exceeds $5,000,000, diversity of citizenship exists between at least one class member and one defendant, 28 U.S.C. § 1332(d)(2), and the number of class members is at least 100, *Id.* § (d)(5)(B). Here, Plaintiffs dispute only the amount in controversy. Plaintiffs argue that the CAFA leaves the burden of establishing federal jurisdiction on a removing defendant and that Defendants have not met that burden. Defendants contend that CAFA eliminated any presumption in favor of remand and shifted to Plaintiffs the burden of proving that federal jurisdiction does not exist. Defendants further contend that, even if the burden of proof remains on them, they have provided evidence sufficient to establish that the amount in controversy in each case exceeds $5,000,000.

***2** The statute itself is silent on the issue of whether, under CAFA, a plaintiff seeking remand to state court bears the burden of proving that federal jurisdiction does not exist. The Third Circuit has not yet addressed this issue. The two Circuit Courts that have addressed the issue both held that, under CAFA, the burden of establishing federal jurisdiction remains on the removing defendant. *Antonio Abrego Abrego et al. v. The Dow Chemical Co. et al.*, 443 F.3d 676, 685 (9th Cir.2006); *James Brill v. Countrywide Home Loans, Inc.*, 427 F.3d 446, 448 (7th Cir.2005). This Court need not address this issue, however, because, even assuming that the burden of proof remains on them, Defendants have satisfactorily shown that the amount in controversy in each case exceeds the statutory threshold of $5,000,000.

"Once the proponent of jurisdiction has set out the amount in controversy, only a 'legal certainty' that the judgment will be less forecloses federal jurisdiction." *Brill,* 427 F.3d at 448-449 (citing *St. Paul Mercury Indemnity Co. v. Red Cab Co.,* 303 U.S. 283 (1938)). Here, Defendants have shown that the relief claimed by Plaintiffs amounts to more than $5,000,000 in each case. Defendants' contentions with regard to the amounts in controversy are based on the following: U.S. Census data on the populations of Tennessee and the applicable Kansas counties, U.S. Census data on computer ownership and purchases in the relevant time period, Intel's share of the x86 microprocessor market as alleged in Plaintiffs' Complaints, the average cost of personal computers containing x86 microprocessors, and the relief requested in Plaintiffs' Complaints. The Court finds Defendants' evidence and calculations sufficient to carry their burden to set out the amount in controversy. In response, Plaintiffs have criticized Defendants' calculations, but have not offered their own evidence, calculations, or estimates of the amount in controversy other than the unsupported assertions in their Complaints that their claims do not exceed $5,000,000. Therefore the Court concludes that, in each case, the amount in controversy exceeds $5,000,000. Thus, the Court has jurisdiction to hear these cases under 28 U.S.C. §§ 1332 & 1453. Accordingly, the Court will deny Plaintiffs' Motions.

An appropriate order will be entered.

D.Del.,2006.
In re Intel Corp. Microprocessor Antitrust Litigation
Slip Copy, 2006 WL 1431214 (D.Del.), 2006-1 Trade Cases P 75,282

Briefs and Other Related Documents (Back to top)

- 2006 WL 845944 (Trial Motion, Memorandum

and Affidavit) Reply Memorandum of Cohen Milstein Hausfeld & Toll, the Furth Firm, Hagens Berman Sobol Shapiro, and Saveri & Saveri in Support of their Application to be Appointed Interim Class Counsel (Feb. 14, 2006)

• 2006 WL 845945 (Trial Motion, Memorandum and Affidavit) The National Plaintiffs Group's Reply Memorandum in Further Support of their Motion for Consolidation and Appointment of Interim Class Counsel and Liaison Counsel (Feb. 14, 2006)

• 2006 WL 691255 (Trial Motion, Memorandum and Affidavit) The National Plaintiffs Group's Response in Opposition to the San Francisco Group's Motion for Appointment as Interim Class Counsel (Feb. 7, 2006)

• 2006 WL 691276 (Trial Motion, Memorandum and Affidavit) The National Plaintiffs Group's Motion for Consolidation and Appointment of Interim Class Counsel and Liaison Counsel (Jan. 24, 2006)

• 2006 WL 691277 (Trial Motion, Memorandum and Affidavit) The National Plaintiffs Group's Memorandum of Law IN Support of its Motion for Appointment of Interim Class Counsel and Liaison Counsel and IN Opposition to the San Francisco Group's Motion for Consolidation and Appointment of CO-Lead Counsel and Lia ison Counsel (Jan. 24, 2006)

• 2005 WL 3874305 (Trial Motion, Memorandum and Affidavit) Memorandum of Law in Support of Motion for Consolidation and for Appointment of Co-Lead Counsel and Liaison Counsel (Nov. 10, 2005)

• 1:05md01717 (Docket) (Nov. 9, 2005)

• 2005 WL 2385592 (Trial Pleading) Class Action Complaint (Jul. 12, 2005) Original Image of this Document (PDF)

• 1:05cv00485 (Docket) (Jul. 12, 2005)

END OF DOCUMENT

EXHIBIT F

Slip Copy, 2006 WL 470592 (E.D.Pa.)
(Cite as: Slip Copy)

C

Briefs and Other Related Documents
Only the Westlaw citation is currently available.

United States District Court,E.D. Pennsylvania.
Estelle ROBINSON, et al, Plaintiffs
v.
HOLIDAY UNIVERSAL, INC., et al, Defendants.
No. Civ.A. 05-5726.

Feb. 23, 2006.

David A. Searles, Donovan Searles, LLC, Philadelphia, PA, for Plaintiffs.
Albert G. Bixler, Anita J. Murray, Eckert Seamans Cherin & Mellott, LLC, Philadelphia, PA, for Defendants.

MEMORANDUM AND ORDER

PRATTER, J.

***1** Plaintiffs, Estelle Robinson and Gene M. Swindell, filed a class action complaint on December 6, 2004 in the Pennsylvania Court of Common Pleas for Philadelphia County against Defendants Holiday Universal, Inc. ("Holiday"), Scandinavian Health Spa, Inc. ("Scandinavian"), and Bally Total Fitness Holding Corporation (" Bally Holding"). Their complaint attacks the health club initiation fees charged by the Defendants. Plaintiffs' action was commenced more than two months before the federal Class Action Fairness Act ("CAFA") became effective on February 18, 2005, and the original Defendants were not entitled to remove the action to federal court pursuant to CAFA's removal provisions. After CAFA became effective, however, the Plaintiffs added an additional defendant, Bally Total Fitness Corporation ("BTFC"), which properly and timely removed the case to federal court pursuant to CAFA. The Plaintiffs subsequently voluntarily dismissed BTFC and now request remand to state court. For the reasons set forth below Plaintiffs' motion to remand is denied.

I. FACTS AND PROCEDURAL HISTORY

Plaintiffs Robinson and Swindell filed a class action complaint on December 6, 2004 in the Pennsylvania Court of Common Pleas for Philadelphia County, alleging that Defendants Holiday, Scandinavian, and Bally Holding charged and collected grossly excessive initiation fees in violation of the Pennsylvania Health Club Act, 73 Pa. Cons.Stat. Ann. § 2161 *et seq.,* which regulates health clubs operating within the Commonwealth, and the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Cons.Stat. Ann. § 201-1 *et seq.,* which prohibits unfair or deceptive acts or practices in the conduct of any trade or commerce. The Plaintiffs also articulated claims for unjust enrichment and for declaratory relief.

In Pennsylvania state court, the Plaintiffs requested, and were granted, leave to join Bally Total Fitness Corporation ("BTFC"), a subsidiary of Bally Total Fitness Holding Corporation, as a defendant. Plaintiffs filed their Joinder Complaint adding BTFC as a defendant on September 30, 2005. On October 28, 2005, BTFC filed a timely notice of removal based on the amount in controversy and minimum diversity of citizenship contemplated by CAFA.

Thereafter, Plaintiffs, apparently in an attempt to have the case remanded to state court, voluntarily dismissed defendant BTFC from the case on November 4, 2005, and, on November 10, 2005, Plaintiffs filed here the motion to remand pursuant to 28 U.S.C. § 1447(c). Plaintiffs claim that the dismissal of BTFC as a defendant dissolved the Court's basis for jurisdiction under CAFA because, prior to BTFC's joinder, none of the original Defendants would have been entitled to remove the case under CAFA. Plaintiffs also argue that remand is appropriate due to considerations of judicial economy, fairness, and efficiency.

II. DISCUSSION

A. BTFC Properly Removed Under the Class Action Fairness Act

*2 CAFA "permits defendants to remove certain class actions to federal court if minimal diversity of citizenship exists." *Knudsen v. Liberty Mut. Ins. Co.,* 411 F.3d 805, 806 (7th Cir.2005). Specifically, CAFA provides that district courts shall have original jurisdiction over any class actions where: (1) at least one member of the plaintiff class is diverse from any defendant; (2) the aggregate amount in controversy exceeds $5,000,000; and (3) the proposed plaintiffs class contains 100 or more members. 28 U.S.C. § 1332(d)(2)(A), (d)(5). The parties here do not dispute that CAFA's numerosity and amount in controversy requirements are met in this case.

CAFA is not retroactive; it only applies to actions commenced after February 18, 2005. Pub.L. 109-2, § 9; *Exxon Mobil Corp. v. Allapattah Servs.,* ---U.S. ----, ----, 125 S.Ct. 2611, 2628, 162 L.Ed.2d 502 (2005); *Natale v. Pfizer, Inc.,* 424 F.3d 43, 44 (1st Cir.2005); *Bush v. Cheaptickets, Inc.,* 425 F.3d 683, 684 (9th Cir.2005). Although CAFA does not define when a class action is "commenced," many courts have held that, for CAFA jurisdictional purposes, a class action commences when it begins in state court. *Natale,* 424 F.3d 43 at 44; *Bush,* 425 F.3d at 686 ("CAFA's 'commenced' language surely refers to when the action was originally commenced in state court."); *Dinkel v. Gen. Motors Corp.,* No. 05-190-P-H, 2005 U.S. Dist. LEXIS 27237, at *6 (D.Me. Nov.9, 2005). Under the Pennsylvania Rules of Civil Procedure, "[a]n action may be commenced by filing with the prothonotary (1) a praecipe for a writ of summons, or (2) a complaint." Pa.R.C.P. 1007.

When a plaintiff adds a new defendant, a new action is "commenced" for purposes of that defendant. *See Adams v. Fed. Materials Co., Inc.,* No. 5:05-cv-90R, 2005 U.S. Dist. LEXIS 15324, at *13 (W.D.Ky. July 28, 2005) ("Plaintiffs' decision to add ... a defendant presents precisely the situation in which it can be and should be said that a new action has 'commenced' for purposes of removal pursuant to the CAFA."); *Schorsch v. Hewlett Packard Co.,* 417 F.3d 748, 749 (7th Cir.2005) ("[A] defendant added after February 18 could remove because suit against it would have been commenced after the effective date."); *Knudsen v. Liberty Mutual Ins. Co.,* 411 F.3d 805, 807 (7th Cir.2005). As stated in *Adams,* allowing a newly-added defendant a window of time for exercising its removal rights "is both a logical extension of pre-existing removal practice and in keeping with the general intent of Congress in passing the CAFA-that is, extending the privilege of removal to federal district courts to defendants in large class actions on the basis of minimal diversity." Thus, in this case, there are two relevant "commencement" dates: (1) December 6, 2004 when the lawsuit was filed against the original three Defendants; and (2) September 30, 2005, when the complaint was filed against BTFC as a new defendant.[FN1] Here, the simple fact of the matter is that the Plaintiffs did not file a complaint against BTFC until September 28, 2005, well after the effective date of CAFA. Thus, for BTFC, the post-CAFA filing of a complaint against it "opened a new window of removal," which it used to timely remove the case.[FN2] *Knudsen,* 411 F.3d at 807.

FN1. Plaintiffs assert, without substantial discussion, that the filing of the complaint against BTFC did not "commence" a new action because the joinder of BTFC relates back pursuant to Federal Rule of Civil Procedure 15(c) to the date of the original filing against the three original Defendants. Plaintiffs' joinder complaint added BTFC as a defendant. BTFC, although a wholly owned subsidiary of Bally Holding, is presumed to be a separate entity. *Mellon Bank, N.A. v. Metro Commc'ns, Inc.,* 945 F.2d 635, 643 (3d Cir.1991). Plaintiffs have not proffered any evidence tending to show that BTFC knew or had reason to know that suit would have been brought against it but for a mistake concerning its identity. Fed. R. Civ. P. 15(c)(3)(B); *see e.g., Fry v. Waste Mgmt., Inc.,* No. 94-6865, 1995 U.S. Dist. LEXIS 11792, at *3-4 (E.D.Pa. Aug. 11, 1995). There is no

indication that Bally Holding participated in any misrepresentations or took advantage of the "technicalities" of pleading to act as a buffer between itself and BTFC. *See e.g., Arthur v. Guerdon Indus., Inc.,* No. 85-244, 1990 U.S. Dist. LEXIS 14042, at *6-7 (D.Del.1990). Mere lack of knowledge of a proper party is not enough under the relation back principle. *Olin v. George E. Logue, Inc.,* 119 F.Supp.2d 464, 473 (M.D.Pa.2000).

FN2. BTFC first received notice of the action against it on September 28, 2005, when the joinder complaint was filed in the court of common pleas. Accordingly, BTFC was entitled to its own thirty day period for removal. *See K.S. v. Sch. Dist. of Phila.,* No. 05-4916, 2005 U.S. Dist. LEXIS 29470, at *9 (E.D.Pa. Nov. 22, 2005); *Harper v. Westfield Apartments,* No. 04-2231, 2005 U.S. Dist. LEXIS 5311, at *4 (E.D.Pa. Mar. 30, 2005). BTFC timely filed its notice of removal on October 28, 2005.

B. Voluntary Dismissal of BTFC from Lawsuit Does Not Undo Proper Removal

***3** Plaintiff next argues that, even if the joinder of BTFC constituted a new "commencement" for CAFA purposes, BTFC's dismissal from the case removes the Court's jurisdictional reach entirely. That is, Plaintiffs assert that the case, as it stands now (i.e., after the voluntary dismissal of BTFC) before the Court, was "commenced" against the three remaining defendants well before the effective date of CAFA. Thus, conclude the Plaintiffs, CAFA cannot supply the ground for subject matter jurisdiction because it is not retroactive.

Under CAFA, any single defendant can remove without the consent of the other defendants, and the entire lawsuit is removed, not merely the claims against the removing defendant. Specifically, CAFA provides that "[a] class action may be removed to a district court of the United States ... without regard to whether any defendant is a citizen of the State in which the action is brought, except that such action may be removed by any defendant without the consent of all defendants." 28 U.S.C. § 1453(b). It is the entire "action" that is removable, not just the claims against particular defendants. *Dinkel,* 2005 U.S. Dist. LEXIS 27237, at *12. Thus, when BTFC removed the class action to this Court, it removed the entire class action and not just the claims against it.[FN3]

FN3. This conclusion differs from *Brown v. Kerkhoff,* 2005 U.S. Dist. LEXIS 24346, at *56 (S.D.Iowa Oct. 19, 2005) (holding that addition of removing defendants after effective date of CAFA allowed removal of claims against removal defendants but not original defendants; remanding case after plaintiffs dismissed removal defendants). *See also Dinkel,* 2005 U.S. Dist. LEXIS 27237, at *12 n. 6. The court in *Brown* stated: "Because CAFA is not applicable to [the pre-CAFA defendants], the only way the Court could exercise jurisdiction over them is as pendant parties. " The Court finds that this reasoning is inconsistent with general removal practice as well as the mandates of 28 U.S.C. § 1453(b). Thus, the Court finds unpersuasive the *Brown* court's focus on the inability of the pre-CAFA defendants to remove the action under CAFA rather than the court's subject matter jurisdiction over the entire class action after post-CAFA defendants removed the entire action pursuant to 28 U.S.C. § 1453(b). *See* 28 U.S.C. § 1332(d), 1453(b).

Propriety of remand is "decided[ ] on the basis of the record as it stands at the time the petition for removal is filed." *Westmoreland Hosp. Ass'n v. Blue Cross of W. Pa.,* 605 F.2d 119, 123 (3d Cir.1979). Here, as discussed above, BTFC properly removed the entire action to the district court at the time of the filing of the notice of removal because all of the jurisdictional requirements of CAFA were then met: an action was commenced against BTFC after February 18, 2005; minimum diversity was met; the aggregated amount in controversy exceeds $5,000,000; and the

proposed plaintiffs class contains more than 100 members. Plaintiffs cannot now "unring the bell" by dismissing the removing defendant, BTFC, (which Plaintiffs themselves brought into the suit) in an attempt to return the lawsuit to its status on December 6, 2004. The Court had subject matter jurisdiction over the action when it was removed on October 28, 2005, and it continues to have subject matter jurisdiction over it now.

Plaintiffs further argue that remand is proper by analogizing this situation to the operation of 28 U.S.C. § 1447(e), which requires courts to remand cases if a post-removal permissive joinder of additional defendants destroys the court's subject matter jurisdiction.[FN4] Plaintiffs argue that this provision shows that the Court must remand once the plaintiff makes a permitted change in the defendant parties that destroys the court's only basis for subject matter jurisdiction. Plaintiffs' reliance on Section 1447(e) is misplaced, however, as there has been no attempted post-removal joinder of additional defendants, nor has the Court's subject matter jurisdiction been destroyed. Section 1447(e) operates to deny a sought-after result to a plaintiff that endeavors to manipulate subject matter jurisdiction by changing the cast of characters. The Court's ruling herein similarly refuses to reward changes.

> FN4. In its entirety, 18 U.S.C. § 1447(e) provides: "If after removal the plaintiff seeks to join additional defendants whose joinder would destroy subject matter jurisdiction, the court may deny joinder, or permit joinder and remand the action to the State court."

III. CONCLUSION

***4** For the foregoing reasons, the Court finds that the Defendants have met their burden of showing that removal was proper and the Court has subject matter jurisdiction, and there are no doubts that must be resolved in favor of remand. *Schwartz v. Comcast Corp.*, No. 05-2340, 2005 U.S. Dist. LEXIS 15396, at *14 (E.D.Pa. July 29, 2005). Thus, Plaintiffs' Motion for Remand will be denied. An appropriate Order consistent with this Memorandum follows.

ORDER

AND NOW this 23rd day of February, 2006, upon consideration of Plaintiffs' Motion to Remand (Docket No. 4), Defendants' Response (Docket No. 10), Plaintiffs' Reply (Docket No.11), and Defendants' Sur-Reply (Docket No. 12), it is hereby ORDERED that Plaintiffs' Motion to Remand is DENIED. It is FURTHER ORDERED that Plaintiffs shall file and serve on opposing counsel their Response, if any, to Defendants' Motion to Dismiss (Docket No. 2) no later than twenty-one (21) days from the date of this Order.

E.D.Pa.,2006.
Robinson v. Holiday Universal, Inc.
Slip Copy, 2006 WL 470592 (E.D.Pa.)

Briefs and Other Related Documents (Back to top)

- 2006 WL 1382045 (Trial Motion, Memorandum and Affidavit) Defendants' Reply in Support of Rule 12(b)(6) Motion to Dismiss Plaintiffs' Joinder Complaint-Class Action (Mar. 27, 2006) Original Image of this Document (PDF)
- 2006 WL 1030966 (Trial Pleading) Plaintiffs' Answer to Defendants' Motion to Dismiss Complaint Pursuant to Fed. R. Civ. P. 12(b)(6) (Mar. 20, 2006) Original Image of this Document with Appendix (PDF)
- 2005 WL 3723878 (Trial Motion, Memorandum and Affidavit) Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion for Remand (Nov. 28, 2005) Original Image of this Document (PDF)
- 2005 WL 3723875 (Trial Motion, Memorandum and Affidavit) Motion (Nov. 10, 2005) Original Image of this Document (PDF)
- 2005 WL 3723870 (Trial Motion, Memorandum and Affidavit) Motion (Nov. 3, 2005) Original Image of this Document with Appendix (PDF)
- 2:05cv05726 (Docket) (Oct. 28, 2005)

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EXHIBIT G

Slip Copy, 2006 WL 487915 (E.D.Pa.)
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United States District Court,E.D. Pennsylvania.

Adam SCHWARTZ
v.
COMCAST CORP.
No. Civ.A. 05-2340.

Feb. 28, 2006.

Michael H. Landis, Smolow & Landis, Trevose, PA, for Adam Schwartz.
Michael W. McTigue, Jr., Michael P. Daly, Drinker, Biddle & Reath LLP, Philadelphia, PA, for Comcast Corporation.

MEMORANDUM

ONEILL, J.

***1** Plaintiff, Adam Schwartz, filed a class action complaint on April 18, 2005 in the Court of Common Pleas for Philadelphia County alleging that defendant, Comcast Corporation, breached its contract with plaintiff, was unjustly enriched, and violated Pennsylvania's Consumer Protection Law by failing to provide high speed internet service to various businesses and residents in Pennsylvania in violation of its express and implied promises in the subscription agreement: (1) to provide "service that was 'always on', 24 hours a day, 7 days per week, 365 days per year"; (2) not to charge for services not rendered; and (3) in the event payment was received for services not rendered, to issue refunds. Defendant filed a notice of removal under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d) (2006). Thereafter, plaintiff filed an amended complaint and motion to remand.

I subsequently held in my memorandum and Order of July 28, 2005 that the issue of subject matter jurisdiction must be determined according to allegations of citizenship set forth in plaintiff's original complaint and that, notwithstanding its legislative history, CAFA did not shift the long standing burden of proof from a removing defendant to a remanding plaintiff. *Schwartz v. Comcast Corp.,* No. 05-2340, 2005 WL 1799414 (E.D.Pa. Jul.28, 2005). I also found that plaintiff's first set of interrogatories was not sufficiently tailored to lead to the discovery of the citizenship of plaintiff's proposed class members. *Id.* I therefore ordered plaintiff to amend these interrogatories and serve them upon defendant. *Id.*

Having dispensed with defendant's motion for partial reconsideration in my Order of December 8, 2005, I now consider plaintiff's motion to remand in light of: (1) the discovered evidence with respect to the citizenship of the plaintiff proposed class members, attached to plaintiff's response to defendant's motion for partial reconsideration (Docket Nos. 19 and 20); (2) plaintiff's arguments that the evidence does not support minimal diversity and that the Court should decline to exercise its jurisdiction, discussed on pages 9-13 of plaintiff's response (Docket No. 19); (3) defendant's arguments that remand is not appropriate irrespective of the burden of proof, discussed on pages 6-12 of defendant's reply (Docket No. 21); (4) plaintiff's supplemental memorandum in support of remand (Docket No. 23); and (5) defendant's supplemental brief in opposition to plaintiff's motion to remand (Docket No. 24). The facts of this case are discussed in my memorandum and Order of July 28, 2005.

STANDARD OF REVIEW

The Court of Appeals has held that "[t]he party asserting jurisdiction bears the burden of showing the action is properly before the federal court" and that "[t]he statute governing removal, 28 U.S.C. § 1441, must be strictly construed against removal." *Sikirica v. Nationwide Ins. Co.,* 416 F.3d 214, 219 (3d Cir.2005). The burden of establishing removal

jurisdiction therefore rests with the removing defendant, here Comcast. CAFA has not altered this longstanding rule. *Brill v. Countrywide Home Loans, Inc.*, 427 F.3d 446, 448 (7th Cir.2005).

DISCUSSION

***2** Comcast argues that remand is not proper in this case because the limited class discovery demonstrates that less than one third of plaintiff's putative class members are citizens of the same state. *See* 28 U.S.C. § 1332(d)(2)-(3) (2006). Schwartz argues that I should decline to exercise jurisdiction because the discovery shows that more than two thirds of the class are Pennsylvania citizens. I conclude that subject matter jurisdiction is proper in this Court under the Class Action Fairness Act ("CAFA"), 28 U.S.C. § 1332(d) (2005) , because I find the evidence to show that less than one third of plaintiff's class are citizens of Pennsylvania.

CAFA generally "permits defendants to remove certain class actions to federal court if minimal diversity of citizenship exists." *Knudsen v. Liberty Mut. Ins. Co.*, 411 F.3d 805, 805 (7th Cir.2005). Specifically, CAFA provides that district courts shall have original jurisdiction of class actions in which: (1) the number of members of the proposed plaintiff classes contain 100 or more members, § 1332(d)(5); (2) the aggregate amount in controversy [FN1] exceeds five million dollars; and (3) at least one member of the plaintiff class is diverse from at least one defendant, § 1332(d)(2).[FN2] Neither party disputes that CAFA's numerosity, amount in controversy, and minimal diversity requirements are met in this case (at least one class member is diverse from Comcast). Comcast argues that Schwartz's broad class definition includes not only citizens of Pennsylvania, but also citizens of other states who are merely "doing business" in Pennsylvania or temporarily "residing" in Pennsylvania. Therefore, Comcast argues that this case is properly removed to this Court because " there is minimal diversity of citizenship and the aggregate alleged amount in controversy exceeds $5,000,000."

FN1. 28 U.S.C. § 1332(d)(6) provides: "In any class action, the claims of the individual class members shall be aggregated to determine whether the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs." CAFA thus abrogates the rule against aggregating claims to meet the jurisdictional limit. *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, Nos. 04-7 & 04-79, --- U.S. ----, 125 S.Ct. 2611, at *2628, 162 L.Ed.2d 502 (June 23, 2005).

FN2. 28 U.S.C. § 1332(d)(2) provides:
The district courts shall have original jurisdiction of any civil action in which the matter in controversy exceeds the sum or value of $5,000,000, exclusive of interest and costs, and is a class action in which-
(A) any member of a class of plaintiffs is a citizen of a State different from any defendant;
(B) any member of a class of plaintiffs is a foreign state or a citizen or subject of a foreign state and any defendant is a citizen of a State; or
(C) any member of a class of plaintiffs is a citizen of a State and any defendant is a foreign state or a citizen or subject of a foreign state.

However, CAFA provides for three exceptions to the general diversity rule. Under the so called " home state controversy" exception, district courts must decline to exercise jurisdiction where two thirds or more of the members of the proposed plaintiff classes, and the primary defendants, are citizens of the original filing state. § 1332(d)(4)(B). Similarly, under the so called "local controversy" exception, district courts must decline jurisdiction where four circumstances are met: (I) greater than two thirds of the members of the proposed plaintiff classes are citizens of the original filing state; (II) at least one defendant is a defendant from whom members of the proposed plaintiff class seek significant relief, whose alleged conduct forms a significant basis of the asserted claims, and who is a citizen of the original filing state; (III) the principal injuries resulting from the alleged conduct of each

defendant were incurred in the original filing state; and (IV) no other class action asserting the same or similar factual allegations has been filed against any of the defendants within the three years preceding the filing of the instant class action. § 1332(d)(4)(A) .[FN3] Under the so called "interests of justice" exception district courts may, "in the interests of justice and looking at the totality of the circumstances," decline to exercise jurisdiction over a class actions in which greater than one-third but less than two-thirds of the total members of all proposed plaintiff classes and the primary defendants are citizens of the State in which the action was originally filed. In considering the interests of justice and examining the totality of the circumstances, district courts are guided by six factors:

FN3. 28 U.S.C. § 1332(d)(4) provides:
A district court shall decline to exercise jurisdiction under paragraph (2)-
(A)(i) over a class action in which-
(I) greater than two-thirds of the members of all proposed plaintiff classes in the aggregate are citizens of the State in which the action was originally filed;
(II) at least 1 defendant is a defendant-
(aa) from whom significant relief is sought by members of the plaintiff class;
(bb) whose alleged conduct forms a significant basis for the claims asserted by the proposed plaintiff class; and
(cc) who is a citizen of the State in which the action was originally filed; and
(III) principal injuries resulting from the alleged conduct or any related conduct of each defendant were incurred in the State in which the action was originally filed; and
(ii) during the 3-year period preceding the filing of that class action, no other class action has been filed asserting the same or similar factual allegations against any of the defendants on behalf of the same or other persons; or
(B) two-thirds or more of the members of all proposed plaintiff classes in the aggregate, and the primary defendants, are citizens of the State in which the action was originally filed.

***3** (A) whether the claims asserted involve matters of national or interstate interest;
(B) whether the claims asserted will be governed by laws of the State in which the action was originally filed or by the laws of other States;
(C) whether the class action has been pleaded in a manner that seeks to avoid Federal jurisdiction;
(D) whether the action was brought in a forum with a distinct nexus with the class members, the alleged harm, or the defendants;
(E) whether the number of citizens of the State in which the action was originally filed in all proposed plaintiff classes in the aggregate is substantially larger than the number of citizens from any other State, and the citizenship of the other members of the proposed class is dispersed among a substantial number of States; and
(F) whether, during the 3-year period preceding the filing of that class action, 1 or more other class actions asserting the same or similar claims on behalf of the same or other persons have been filed.

§ 1332(d)(3). Schwartz argues that CAFA excludes federal jurisdiction over this case because the class definition in his amended complaint falls within the "home state controversy," "local controversy," or " interests of justice" exceptions.

In his complaint, Schwartz defined the plaintiff class as: "All persons and entities residing or doing business in the Commonwealth of Pennsylvania who subscribed to Comcast's high-speed internet service during the period April 7, 2004 to April 14, 2005." Being a citizen of Pennsylvania is not a qualification for class membership under the definition stated in the original complaint. As discussed in my July 28, 2005 memorandum and Order, Schwartz's allegations of residence are not sufficient for purposes of establishing citizenship. *See, e.g., Krasnov v. Dinan,* 465 F.2d 1298, 1300 (3d Cir.1972) ("Where one lives is prima facie evidence of domicile, but mere residency in a state is insufficient for purposes of diversity.").[FN4]

FN4. This rule applies notwithstanding the language of the Fourteenth Amendment: "

> All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside," U.S. Const, amend. XIV, § 1. *See Robertson v. Cease,* 97 U.S. 646, 650, 24 L.Ed. 1057 (1878) ("We perceive nothing in either the language or policy of the Fourteenth Amendment which requires or justifies us in holding that the bare averment of the residence of the parties is sufficient, *prima facie,* to show jurisdiction. ").

Hypothetically speaking, there may be numerous members of the proposed class who are citizens of different states but who resided or did business in Pennsylvania and subscribed to Comcast's high-speed internet service during the relevant time period. Comcast therefore argues three points: (1) that no reasonable amount of discovery could possibly reveal with precision the number of those subscribers who were "doing business" or "residing" in Pennsylvania during the relevant time period; (2) that the facts reveal that the putative class, as defined by Schwartz, would likely be comprised predominantly of non-Pennsylvania citizens; (3) that this case involves a nationwide internet service disruption, not a local controversy.

With respect to its first argument, Comcast argues the CAFA's legislative history states that in making jurisdictional determinations "a federal court may have to engage in some fact-finding, not unlike what is necessitated by the existing jurisdictional statutes." Judiciary Committee Report on Class Action Fairness Act, S.Rep. No. 109-14, at 44 (1st Sess.2005). The Senate Judiciary Committee acknowledged that "in some instances, limited discovery may be necessary to make these determinations" but cautioned that "these jurisdictional determinations should be made largely on the basis of readily available information. " *Id.* In the Committee's view:

***4** Allowing substantial, burdensome discovery on jurisdictional issues would be contrary to the intent of these provisions to encourage the exercise of federal jurisdiction over class actions. For example, in assessing the citizenship of the various members of a proposed class, it would in most cases be improper for the named plaintiffs to request that the defendant produce a list of all class members (or detailed information that would allow the construction of such a list), in many instances a massive, burdensome undertaking that will not be necessary unless a proposed class is certified. Less burdensome means (e.g., factual stipulations) should be used in creating a record upon which the jurisdictional determinations can be made.

Id. Comcast thus argues that any attempt to ascertain the precise composition of the putative class would require a Herculean undertaking and the parties and the Court should not be conducting mini-trials to determine individual class members' citizenship.[FN5] Although I am cautious about relying upon this legislative history, as discussed in my memorandum and Order of July 28, 2005, I will make a jurisdictional determination based upon the evidence available at this stage of the litigation.

> FN5. Comcast also argues that Schwartz's claims are barred as a matter of law because the language of the subscriber agreement disclaims any promise of uninterrupted service and provides remedies only in the event of twenty four hour service disruptions. *See Kaplan v. Cablevision of Pa., Inc.,* 448 Pa.Super. 306, 671 A.2d 716, 720 (Pa.Super.Ct.1996) (affirming dismissal of claims stemming from interruption of cable services because parties' subscriber agreement contained no "provisions which suggest that the [defendants] obligated themselves to provide continuous, uninterrupted service or to automatically provide rebates for interruptions in service"); *Shapiro v. Comcast Corp.,* No. MIS-L-2034-02 (Sup.Ct.N.J. Oct. 14, 2003); *Mentzel v. Comcast,* No. 02-038569-CP (Mich.Cir.Ct. Jul. 7, 2003). I will not discuss the merits of this case without first determining whether I have subject matter jurisdiction.

With respect to its second argument, Comcast argues that the evidence demonstrates that less than

one third of the putative class are citizens of Pennsylvania. A person is considered a citizen of a state if that person is domiciled within that state and is a citizen of the United States. *See generally,* Charles A. Wright, Arthur R. Miller & Edward H. Cooper, 13B Federal Practice & Procedure § 3611, at 507. For purposes of determining diversity, state citizenship of a natural person is treated as synonymous with domicile. *Krasnov v. Dinan,* 465 F.2d 1298, 1300 (3d Cir.1972). Domicile, however, is not necessarily synonymous with residence; one can reside in one place and be domiciled in another. *Mississippi Band of Choctaw Indians v. Holyfield,* 490 U.S. 30, 48, 109 S.Ct. 1597, 104 L.Ed.2d 29 (1989); *Krasnov,* 465 F.2d at 1300 ("Where one lives is prima facie evidence of domicile, but mere residency in a state is insufficient for purposes of diversity.") (internal citations omitted).

Two elements typically are necessary to establish domicile: (1) residence; and (2) an intent to make the place of residence one's home. *Krasnov,* 465 F.2d at 1300. Thus, a person normally acquires a domicile voluntarily by residing in a place with an intention to remain there indefinitely. *Id.* at 1300-01; Federal Practice & Procedure § 3612, at 526 ("It is often said that the domicile of a person is the place where an individual has his true, fixed home and principal establishment, and to which, whenever he is absent, he has the intention of returning.").

Comcast asserts that the evidence shows that it has approximately 8, 142,000 internet subscribers in the United States and that a large number of these subscribers could be considered either to be " residing" or "doing business" in Pennsylvania. Comcast also asserts that there are approximately 200,000 citizens of other states who are "doing business" in Pennsylvania by commuting to work in Pennsylvania and countless numbers of citizens from other states who are "doing business" with Pennsylvania via the internet. Comcast thus argues that "[b]ecause Comcast provides Internet service to over 8,000,000 subscribers nationwide, the number of putative class members 'doing business' in Pennsylvania from other states likely *dwarfs* the number of subscribers who 'received service in Pennsylvania." ' (emphasis by defendant). By contrast, Schwartz focuses on Comcast's residential subscribers and argues that at least 84 % of the putative class are domiciled in and citizens of Pennsylvania. [FN6]

> FN6. The parties have stipulated to treating the discovered jurisdictional information as confidential and have filed their briefs and attached evidence under seal because Comcast believes this commercial information to be highly sensitive and an unfair insight into its business operations for its competitors. Therefore, I have placed this information in a sealed appendix to this memorandum and Order.

***5** In regard to residence, Schwartz argues that because Comcast's Service Subscriber Agreement provides that residential service is delivered to the customer's residence 98 % of the "residential service customers were also Pennsylvania residents, and almost all of them conducted their personal business affairs here in Pennsylvania." Comcast does not dispute the residence of the putative class. In regard to intent, Schwartz argues that because 86.5 % of the class members maintained Comcast service over a five month period they intended to remain resident in Pennsylvania. Accordingly, Schwartz argues that these class members were domiciled in and, thus, citizens of Pennsylvania.

The determination of a person's domicile is a fact specific question. In addition to one's residence, courts frequently consider a number of nonconclusive factors, including: (1) voting registration and voting practices; (2) location of personal and real property; (3) location of brokerage and bank accounts; (4) membership in unions, fraternal organizations, churches, clubs, and other associations; (5) place of employment or business; driver's license and automobile registration; and (6) payment of taxes. *Krasnov,* 465 F.2d at 1301; Federal Practice & Procedure § 3612, at 530-31. Although neither party has asserted any of these specific factors, Schwartz appears to argue that a subscriber's decision to maintain Comcast service at their Pennsylvania residence is indicative of his or her intent to remain

in Pennsylvania indefinitely.

I disagree. The factors described above are suggestive of an intent to remain in a certain state and, thus, domicile, because they are features of a permanent residence. Typically, one does not vote/register to vote, purchase personal and real property, open brokerage and bank accounts, join associations, or become employed or open a business unless one intends to remain in that state indefinitely. Unlike those factors, a subscription to internet service is not indicative of an intent to remain permanently in a state. Internet service has become a standard necessity in many individuals' homes; one subscribes to internet service in much the same way that one orders telephone, electric, cable, gas, water, and other services upon moving into a house or apartment. None of these standard services is suggestive of an intent to remain in a specific state. One need only look at the hundreds of thousands of out of state students at Pennsylvania's colleges and universities who maintain internet service (as well other necessary services) over the course of four years but only intend to remain in Pennsylvania during the period of their education. An intent to maintain internet service does not suggest an intent to remain permanently in one state.

Schwartz adds three other strings to his bow. First, he argues that "the very fact that the class received [residential] high speed internet service at locations in Pennsylvania is evidence of domicile [because] [b]y its nature, high speed internet service involves a permanent and fixed setup, rather than one that is mobile or transient." This argument is discounted quickly because the required hardware for internet access (cable and/or telephone lines) is a standard feature of most homes. Second, he asserts that, according to the United States Census Bureau studies of population mobility, only 2 to 3 % of the population changes residence to a different state each year to suggest that the other 97 to 98 % of the population intends to remain in the same state. However, the annual population shift has no bearing on the intent of the other 97 to 98 % to remain in a specific state indefinitely. The 97 to 98 % of the population may remain in one state for many years without any intent to remain there permanently. Third, he argues that of the approximate 2 % of persons or entities receiving nonresidential service in Pennsylvania "[i]t is unlikely that all of these non-residential customers are also non-Pennsylvania citizens." There is no evidence to support this argument.

***6** In sum, each of Schwartz's arguments is premised on the assumption that residence is an effective proxy for domicile. I decline to draw such a parallel. *See Krasnov,* 465 F.2d at 1300 ("[M]ere residency in a state is insufficient for purposes of diversity."). Absent evidence of any factor that bears on the class members' intent to remain in Pennsylvania, I am unable to determine the domicile of plaintiff's residential class members. Moreover, Schwartz appears to assume that only class members who subscribe to Comcast's nonresidential internet service in Pennsylvania could be considered to be Comcast internet subscribers that are "doing business" in Pennsylvania. Because of this assumption, Schwartz fails to address the millions of Comcast internet subscribers across the nation that are not Pennsylvania citizens and could be considered to be "doing business" in Pennsylvania. Even discounting Comcast's assertion-that the April internet service disruption affected over eight million of its customers nationwide-for those subscribers who cannot be considered to be "doing business" in Pennsylvania and taking at face value Schwartz's assertion-that the 98% of residential service customers are citizens of Pennsylvania-I find it most likely that the putative class comprises less than one third of Comcast's nationwide subscribers that could be considered to be "residing" or "doing business" in Pennsylvania. Federal jurisdiction is further supported by a national interest in protecting the millions of citizens from many states whose contractual rights were allegedly violated by Comcast's nationwide service disruption. Subject matter jurisdiction in this Court is proper under CAFA and Schwartz's motion to remand will be denied.

I need not address Schwartz's arguments that remand is appropriate under the "home state controversy" exception (requires "two-thirds or more" of putative class be citizens of same state, §

1332(d)(4)(B)), "local controversy" exception (" greater than two-thirds," § 1332(d)(4)(A)), or " interests of justice" exception ("greater than one-third but less than two thirds," § 1332(d)(3)) because I conclude that less than one third of the putative class members are citizens of Pennsylvania. An appropriate order follows.

ORDER

AND NOW, this 28th day of February 2006, upon consideration of plaintiff's motion to remand, in light of the evidence with respect to the citizenship of the plaintiff proposed class members (attached to plaintiff's response), plaintiff's response to defendant's motion for partial reconsideration and defendant's reply thereto, plaintiff's supplemental memorandum in support of remand, and defendant's supplemental brief in opposition thereto, and for the reasons set forth in the accompanying memorandum, it is ORDERED that plaintiff's motion to remand is DENIED.

E.D.Pa.,2006.
Schwartz v. Comcast Corp.
Slip Copy, 2006 WL 487915 (E.D.Pa.)

Briefs and Other Related Documents (Back to top)

• 2006 WL 1358318 (Trial Motion, Memorandum and Affidavit) Plaintiff's Brief in Opposition to Comcast Corporation's Motion to Compel Arbitration (Apr. 27, 2006) Original Image of this Document (PDF)
• 2006 WL 1358319 (Trial Motion, Memorandum and Affidavit) Plaintiff's Motion for Class Certification (Apr. 27, 2006) Original Image of this Document (PDF)
• 2005 WL 2685373 (Trial Motion, Memorandum and Affidavit) Defendant Comcast Corporation'S Motion for Partial Reconsideration of this Court'S Order Dated July 28, 2005 and Entered July 29, 2005 (Aug. 12, 2005) Original Image of this Document (PDF)
• 2005 WL 1403726 (Trial Motion, Memorandum and Affidavit) Order (May 25, 2005)
• 2:05cv02340 (Docket) (May. 18, 2005)

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EXHIBIT H

Not Reported in F.Supp., 1995 WL 695109 (E.D.Pa.)
(Cite as: Not Reported in F.Supp.)

H

Briefs and Other Related Documents
Only the Westlaw citation is currently available.

United States District Court, E.D. Pennsylvania.

Nagesh SHIRSAT
v.
MUTUAL PHARMACEUTICAL CO., INC.

No. CIV.A 93-3202.

Nov. 21, 1995.

MEMORANDUM AND ORDER

HUTTON, J.

***1** Presently before the Court are the motion of defendant Mutual Pharmaceutical Co., Inc. ("Mutual ") to stay discovery and proceedings and the opposition of the plaintiff, Nagesh Shirsat ("Shirsat") thereto.

I. *BACKGROUND*

This civil action was commenced on June 15, 1993 and involves Shirsat's allegations that he was wrongfully discharged from his employment with Mutual. Shirsat alleges that Mutual terminated his employment in retaliation for his reporting to the authorities certain of Mutual's practices in violation of the Federal Food, Drug, and Cosmetic Act and the rules and regulations of the Federal Food and Drug Administration. After Shirsat filed this case, attorneys for the government filed a motion to stay Shirsat's civil action pending the government's ongoing criminal investigation of Mutual. Shirsat did not oppose the stay based, *inter alia,* on his understanding that the issues to be litigated in his civil case might be narrowed by the resolution of the criminal investigation. Accordingly, this Court issued a stay in January of 1994.

As a result of the government's criminal investigation, Mutual pleaded guilty to a seven count indictment and entered into a non-appealable plea agreement in which Mutual agreed to pay a fine of $3.25 million. In addition to the government's indictment against Mutual, the government also indicted four employees of Mutual. The government's case against the employees proceeded to trial and resulted in the conviction of two of the employees.

Following the conclusion of the employees' criminal trial, this Court lifted the stay in this case in May of 1995. Subsequently, the convicted employees moved for a new trial. Mutual now argues that the stay should be reinstated until the criminal proceedings of the employees, including a new trial (if there is one) and sentencing, have been fully concluded. Since the time for the resolution of the criminal proceedings is unknown, Mutual proposes to advise the Court in ninety days of the status of the proceedings.

II. *DISCUSSION*

"[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with the economy of time and effort for itself, for counsel, and for litigants." *Texaco, Inc. v. Borda,* 383 F.2d 607, 608 (3d Cir.1967) (quoting *Landis v. North American Co.,* 299 U.S. 248, 254-55 (1936)). A stay is an extraordinary measure, *United States v. Breyer,* 41 F.3d 884, 893 (3d Cir.1994), and calls for a court to exercise judgment and weigh competing interests. *Texaco,* 383 F.2d at 608. In determining whether to stay civil proceedings, a court should consider the following factors: (1) the interest of the plaintiff in proceeding expeditiously with the civil action as balanced against the prejudice to the plaintiff from delay; (2) the burden on defendant; (3) the convenience to the courts; (4) the interest of persons not parties to the civil litigation; and (5) the public interest. *Springfield Township v. Kuss,* C.A. No. 93-1629, 1993 WL

430421, at *1 (E.D.Pa. Oct. 21, 1993); *Golden Quality Ice Cream Co. v. Deerfield Specialty Papers, Inc.,* 87 F.R.D. 53, 56 (E.D.Pa.1980). The Court finds that these factors weigh against issuing a stay.

A. *Plaintiff's Interest*

***2** A plaintiff enjoys the right to pursue his case and to vindicate his claim expeditiously. *Golden Quality,* 87 F.R.D. at 56. When a case is delayed, a plaintiff may suffer prejudice as a result of the death or relocation of witnesses and the fading of witnesses' memories. *See In re Mid-Atlantic Toyota Antitrust Litig.,* 92 F.R.D. 358, 359 (D.Md.1981).

Mutual argues that Shirsat will not be prejudiced by the requested stay because: (1) Shirsat's interests in awaiting the resolution of the criminal proceedings remain the same now as they were when the Court issued the previous stay; (2) the requested stay is of limited duration because Mutual proposes to submit a status report of the criminal proceedings to the Court in ninety days; (3) Shirsat has not engaged in efforts to achieve a swift resolution of the case since the lifting of the previous stay; and (4) a possibility exists that the resolution of the criminal proceedings will narrow the issues to be litigated in the civil case.

The Court finds Mutual's arguments unconvincing. First, Shirsat's interests are considerably different now than they were when the Court issued a stay in January of 1994 for the simple reason that nearly two years have passed since then. At this point, therefore, the prejudice to Shirsat of a further stay due to the unavailability of witnesses and the deterioration of witnesses' memories looms that much more significantly. In addition, in an affidavit in support of his memorandum of law, Shirsat affirms that he has not been able to find employment in the pharmaceutical industry as a result of the circumstances underlying this litigation. (Shirsat Aff. ¶ 10.) Shirsat affirms that since he commenced this action, his unemployment has caused him severe financial and emotional strain. (Shirsat Aff. ¶¶ 10, 11.) Accordingly, the Court finds that Shirsat's interests in expeditiously proceeding with his case are significantly more than they were when the Court issued the stay in January of 1994.

Second, the Court is unconvinced that Mutual's requested stay is for a limited duration of time. While Mutual proposes to advise the Court of the status of the criminal proceedings in ninety days, Mutual does not submit anything indicating that it expects the criminal proceedings to be resolved in or about that time. Without such an indication, the length of the stay Mutual requests is uncertain. To the extent that Mutual's argument is that the Court can lift the stay after ninety days in the event the criminal proceedings have not been resolved in that time, Mutual's request would be arbitrary. It would penalize Shirsat without any concomitant benefits to Mutual, its employees, or the courts.

Third, the Court does not credit Mutual's conclusory allegation that Shirsat has not engaged in efforts to achieve a swift resolution of the case since the lifting of the stay. Shirsat's counsel has certified to the Court that initial discovery and trial preparation have been conducted, and counsel has certified his belief that this case will be ready for trial within ninety days. (Belland Cert. ¶¶ 8-10.)

***3** Fourth, and final, in light of the fact that Mutual, the only defendant in this civil case, signed a non-appealable plea agreement in the criminal case and is no longer involved in that case, the Court is unconvinced that the resolution of the criminal proceedings will narrow any issues in this civil action. To the extent that Mutual's relationship with its employees may have a bearing on this case, the Court notes that the employees' motion for a new trial is based on errors in the jury charge and the erroneous introduction of one piece of evidence, which is claimed to have been prejudicial. (Def.'s Reply Mem. Ex. C). Therefore, the Court does not believe that a second trial (if granted) would raise significantly different issues than those raised in the first trial. Even with the benefit of a completed trial behind it, Mutual has failed to specify what issues would be narrowed by a new trial. Accordingly, the Court finds Mutual's argument conclusory and unconvincing.

B. *Burden on Defendants*

The burden to defendants in litigating both a civil and criminal case simultaneously is usually two-fold. First, the defendants face the burden of being diverted from the preparation of their criminal defense. *See Golden Quality,* 87 F.R.D. at 56. While "we may assume a certain elasticity in the capacity of the various law firms to adjust to the needs of both litigations," intensive civil discovery may "spread thin the time of certain key individuals . .. [who] must be preoccupied with providing essential information to those attempting to mount a defense to the criminal charges." *Id.* Second, the defendants face the risk that the plaintiff will abuse the broad civil discovery rules to gain information useful for the government in the criminal case. *See Golden Quality,* 87 F.R.D. at 57 ("[P]laintiffs have no right to use civil discovery as a pretext for gathering information useful for the criminal cases."); *see also Afro-Lecon, Inc. v. United States,* 820 F.2d 1198, 1203 (Fed.Cir.1987) (in the context where the government is a party to both the civil and criminal cases: "The broad scope of civil discovery may present to both the prosecution, and at times the criminal defendant, an irresistible temptation to use that discovery to one's advantage in the criminal case.").[FN1]

> FN1. The cases are concerned with the *abuse* of discovery. Thus, "[w]hile any action which delays discovery in the civil case might have the incidental effect of limiting the Government's fortuitous access to information arguably relevant in the criminal case, this is not a factor which should or will influence the decision whether to grant a stay." *Golden Quality,* 87 F.R.D. at 57.

Mutual is the only defendant in the civil case. It has signed a non-appealable plea agreement and is not involved in the criminal action any longer. Therefore, the burdens associated with litigating simultaneous civil and criminal cases are inapplicable to Mutual.

C. *Convenience to the Courts*

Simultaneous cases present the potential of duplication of judicial effort. *Golden Quality,* 87 F.R.D. at 57. Thus, if the government's success in the prosecution of the criminal case leads to a possibility that a court will be relieved of a substantial amount of work in the civil case, this factor militates in favor of granting a stay. *Id.* Moreover, convenience to a court will militate in favor of a stay where the outcome of a criminal case can be expected to remove the predicate for the assertions of the Fifth Amendment rights against self-incrimination by potential deponents and lighten the work load of a court to review those assertions. *See id.* at 58; *Mid-Atlantic Toyota,* 92 F.R.D. at 360.

***4** Mutual makes a conclusory argument that the resolution of the criminal case will narrow the issues in this civil case and result in judicial economy. Again, as the Court found in the prior section, this argument is unconvincing because of its generality. Particularly after a full trial, one would expect that a meritorious argument could be made with more specificity. In addition, the Court notes that Mutual has identified only two potential deponents (the two employees who were convicted at trial) who will likely assert their Fifth Amendment privileges at their civil depositions. The Court does not believe that removing the predicate for the Fifth Amendment privileges of these two deponents will substantially lighten its docket.

D. *Interest of Non-Parties*

The interests of non-parties are usually the same as those of the defendants: diversion of resources from their criminal defense and risk of abuse of the civil discovery process. Mutual argues that the interests of the convicted employees militate in favor of granting the stay.

The Court finds that the burdens of the civil proceeding on the convicted employees is not substantial. The Court notes that Mutual and its employees are concerned with the burdens of a re-trial (if granted), not an initial trial. At this stage, much, if not all, of the defense has been

prepared already during the initial trial. Therefore, the burden of spreading thin the time of key individuals is much reduced.

The Court also finds that less drastic alternatives to a stay exist that will adequately protect the convicted employees from abuses of the discovery process. For example, Mutual may apply for protective orders to seal depositions or limit the attendants at a deposition. In addition, the employees can always assert their Fifth Amendment privileges where applicable. Therefore, the interests of Mutual's employees do not weigh heavily in favor of a stay.

E. *Public Interest*

Since the civil case involves a contractual action between two private parties, the Court finds that the public interest does not play a role in its balancing.

III. *CONCLUSION*

After a consideration of the foregoing factors, the Court concludes that Mutual's motion for a stay should be denied because Shirsat's interests weigh heavily against a stay, while the burdens on Mutual, its employees, and the courts in proceeding with the civil case are minimal. An appropriate Order follows.

ORDER

AND NOW, this 20th day of November, 1995, upon consideration of the Defendant's Motion to Stay Discovery and Proceedings, IT IS HEREBY ORDERED that the Defendant's Motion is DENIED.

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Briefs and Other Related Documents (Back to top)

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